File No: LTD/1907

June 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-(1-oxo-2-propen-1-yl)-ω-([1,1'-biphenyl]-2-yloxy)-

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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.

This Public Report is 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
LTD/1907	DIC Australia Pty Ltd	Poly(oxy-1,2-ethanediyl), α-(1-oxo-2-propen-1-yl)-ω-([1,1'-biphenyl]-2-yloxy)-	*ND	< 1 tonne per annum	Component of UV printing inks

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), as adopted for industrial chemicals in Australia, or the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004).

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

Hazard classification	*Hazard statement*
Acute Category 2	H401 – Toxic to aquatic life
Chronic Category 2	H411 – Toxic to aquatic life with long lasting effects

Human health risk assessment
Provided that the recommended controls are being adhered to, 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

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in ink products:
  - Local exhaust ventilation and adequate general ventilation (as specified in Safe Work Australia Guidance Control guidance sheet *P39 Wide-format inkjet printing with solvent-borne inks*)

- 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 as introduced in ink products:
  - Avoid contact with skin and eyes
  - Avoid breathing in vapours

- Compliance with Safe Work Australia Guidance Control guidance sheet *P39 Wide-format inkjet printing with solvent-borne ink*

- 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 as introduced in ink products:
  - Protective clothing
  - Disposable gloves if dermal exposure to the ink 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 of 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

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical;
  - additional information has become available to the person as to the skin sensitisation of the chemical.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from being component of UV printing inks, 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 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)
DIC Australia Pty Ltd (ABN: 12 000 079 550)
323 Chisholm Road
AUBURN NSW 2114

NOTIFICATION CATEGORY
Limited-small volume: chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Analytical data, degree of purity, polymer constituents (Not relevant to this application), residual monomers, impurities, additives/adjuvants, use details, manufacture/import volume.

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
South Korea
USA
Europe
Japan
China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MIRAMER M1142

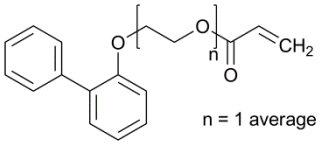
CAS NUMBER
72009-86-0

CHEMICAL NAME
Poly(oxy-1,2-ethanediyl), α-(1-oxo-2-propen-1-yl)-ω-([1,1'-biphenyl]-2-yloxy)-

OTHER NAME(S)
Ethoxylated o-phenylphenol monoacrylate
Polyethylene glycol o-phenylphenyl ether acrylate
OPPEA

MOLECULAR FORMULA
$(C_2H_4O)_nC_{15}H_{12}O_2$

STRUCTURAL FORMULA
The chemical will be introduced in a form that does not meet the definition of a polymer.



MOLECULAR WEIGHT
268.3 Da (where *n* = 1)

ANALYTICAL DATA
Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
>98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	
Boiling Point	380 °C at 101.3 kPa	Calculated using MPBVP (v1.43). Decomposition/polymerisation is expected to occur prior to boiling
Density	1,130 kg/m^3 at 20 °C	SDS
Vapour Pressure	3.62 × 10^{-7} kPa at 25 °C	Calculated using MPBVP (v1.43).
Water Solubility	Not determined	Expected to be low based on predominantly hydrophobic molecular structure
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to hydrolyse under environmental conditions (pH 4–9) based on low expected water solubility
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surface activity
Surface Tension	42 mN/m	Measured*
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on surface activity
Dissociation Constant	Not determined	Contains no dissociable functionalities
Flash Point	165 °C at 101 kPa	SDS
Flammability	Not determined	Not expected to form flammable atmospheres.
Autoignition Temperature	Not determined	No structural alert for autoignition
Explosive Properties	Not determined	No structural alert for explosive properties
Oxidising Properties	Not determined	No structural alert for oxidising properties

* Full study report not provided

DISCUSSION OF PROPERTIES

Reactivity
The notified chemical is expected to be stable under normal conditions of use. The notified chemical will undergo polymerisation under strong UV light.

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 of 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 not be manufactured or reformulated in Australia. The notified chemical will be imported as a component of finished ink products for inkjet printer ink at up to 20% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
DIC Australia Pty Ltd
Miwon Specialty Chemical Co., Ltd (Manufacturer)

TRANSPORTATION AND PACKAGING
The printer cartridges will be transported by road to the notifier's warehouse and then distributed to end-users. The notifier states that the imported inks (in 5 L plastic bottles) will be transported and stored as Dangerous Goods.

USE
The notified chemical will be used as a component of UV-cured digital printing inks (at up to 20% concentration).

OPERATION DESCRIPTION
The notified chemical will be imported as a component of ink in sealed plastic bottles.

End-users will manually pour the ink from bottles into the 5 L ink tanks within the printer. Printer maintenance and handling of the printed substrate will be carried out by service technicians and printer operators, respectively. The notified chemical can be printed onto a variety of substrates including: PVC, polycarbonate, styrene, acrylic, paper, board, wood and aluminium composite. The ink containing the notified chemical will not be available to the public.

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
Storage and transport workers may come into contact with the notified chemical, as a component of ink (≤ 20% concentration), only in the unlikely event of an accident where the packaging is breached.

Printer operators will pour the ink manually into the ink tank of the printing machine. From there the ink will be pumped automatically to the printing head. Workers will service the printer in case of substrate jam and thereby, may be exposed to the notified chemical dermally at up to 20% concentration. Occasional dermal exposure during use of printers could also occur if the printed pages are touched before the ink had been UV-cured. Printer operators will wear impervious gloves during replacement of ink.

Service technicians will wipe the residual ink within printing equipment using rags and solvents. Cleaning rags and used solvents ('dirty solvents') will be disposed of by the printing company through licensed disposal contractors. The notifier states that these workers may have minimal dermal exposure to the notified chemical as a result of any leak and will wear impervious gloves during maintenance operations. Once the ink dries, the notified chemical will be bound to the substrate and is not expected to be bioavailable, thus further dermal

contact should not lead to exposure. Inhalation exposure to the notified chemical is not expected under the proposed use scenario.

6.1.2. Public Exposure

The ink cartridges containing the notified chemical will only be used for commercial purposes. The general public may come into contact with the printed substrate. However, the notified chemical is expected to be UV-cured in the matrix and will not be bioavailable. Therefore, exposure of the public to the notified chemical is not expected to be significant.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration test	non genotoxic

Toxicokinetics

No toxicokinetic data were submitted. Based on the expected low water solubility (due to the predominantly hydrophobic structure) and the low molecular weight (< 500 Da) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur. The notified chemical may also be absorbed across the respiratory tract.

Acrylates 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, and therefore, will not likely cause cumulative toxicity (Patty's Toxicology, 2012).

Acute toxicity

The notified chemical was of low toxicity via the oral route. Although no mortality at the dose level of 2,000 mg/kg bw was observed, prone position, lateral position, subdued behaviour, irregular respiration and lacrimation were recorded in the test animals during first two days following the oral administration.

No acute dermal and inhalation toxicity information was provided for the notified chemical.

Irritation/Sensitisation

The notified chemical contains a functional group which is known to be attributed to the potential for skin/eye irritation and skin sensitisation.

Mutagenicity/Genotoxicity

The notified chemical was not considered to be mutagenic in a bacterial reverse mutation study. In an in vitro mammalian chromosome aberration test, the notified chemical caused a slight but statistically significant increase in the magnitude of the chromosomal aberration only at the highest dose in the presence of metabolic activation. There was no dose-related increase which is required for a clearly positive result. Metaphase analysis data did not indicate any major change in chromatid/chromosome break, exchange or gap in any condition.

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 these 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 chemical gave a positive result in an in vitro mammalian chromosome aberration test, based on the available information, it is not expected to be genotoxic in vivo.

Health hazard classification

Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The manufacturer has applied the following precautionary GHS classifications for the notified chemical: Eye irritation (Category 2) and Skin irritation (Category 2). The risk for skin/eye irritation and/or skin sensitisation cannot be ruled out.

Workers most at risk of exposure to products containing the notified chemical (at < 20% concentration) 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. To minimise occupational exposure to the notified chemical, PPE should be employed, including protective clothing and impervious gloves.

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 chemical. In addition to the local exhaust ventilation proposed by the notifier, the Safe Work Australia (SWA) guidance document, *P39 – Wide-format inkjet printing with solvent-borne inks*, also recommends providing a good standard of general ventilation, and that ventilation equipment is maintained and working effectively.

Overall, provided that adequate workplace controls are in place to reduce potential for exposure to the inks containing the notified chemical, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The ink products containing the notified chemical will not be available to the public. The public may have contact with dry printed materials. Given the public will only be exposed to the notified chemical in non-bioavailable composition, the risk to public health from use of the notified chemical 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 into Australia as a component of finished UV-cured inkjet printer ink; no reformulation or repackaging will occur in Australia. Therefore, no environmental release is expected from manufacturing or reformulation in Australia. Environmental release of the notified chemical during importation, transport and storage is likely to be limited to accidental spills and leaks. In the event of spills, the notified chemical is expected to be collected with adsorbents and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical will be used as a component of UV-cured printing inks for printing onto a variety of non-recyclable substrates. A minor amount of printing ink containing the notified chemical (up to 5%, or 50 kg) will be used for printing onto paper substrates. During use, printing ink containing the notified chemical will be manually transferred into ink tanks within the printer. Printing is expected to be largely enclosed and automated. The notified chemical is expected to be stable within an inert ink matrix on printed substrates once UV-cured.

Environmental release of the notified chemical during use is expected to be limited to accidental spills and leaks and cleaning of printing equipment. It is estimated by the notifier that up to 1% of the annual import volume

(10 kg) may be released as a result of spills and equipment cleaning. Spills and leaks and solid wastes from cleaning will be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will be used in UV-cured printing ink for printing onto a variety of non-recyclable substrates and paper substrates. The majority of the notified chemical is expected to share the fate of the printed articles to which it is bound, and is expected to be disposed of to landfill at the end of their useful lives.

Of the 5% import volume of the notified chemical applied to paper, it is assumed that half of this amount is expected to be disposed of to landfill, and the remainder will undergo paper recycling processes. Empty ink bottles containing residues of the notified chemical will be disposed of to landfill in accordance with local government regulations. It is estimated by the notifier that up to 1% of the annual import volume (10 kg) may be disposed of to landfill as residues in empty containers. Hence, the majority of the notified chemical is expected to be disposed of to landfill, with a potential for some release to sewer through paper recycling processes. During paper recycling processes, waste paper is pulped using a variety of chemical treatments which, amongst other things, will enhance ink detachment from the fibres. Waste water containing the notified chemical will be released to sewer.

7.1.2. Environmental Fate

The majority of the notified chemical in printing ink will be UV-cured and bound within an inert ink matrix, and will share the fate of the printed articles. The majority of the notified chemical is expected to enter the environment from disposal of printed articles to which the printer ink containing the notified chemical is bound. Approximately 2.5% of the notified chemical is expected to be disposed of to landfill as part of printed waste paper (50% × 5% applied to paper substrates). Based on the results of a ready biodegradability study, the notified chemical is not considered readily biodegradable (1.7% in 28 days). For details of the environmental fate study, please refer to Appendix C. The notified chemical is not expected to be bioaccumulative based on its surfactant properties.

Approximately 50% of the paper substrates to which the ink containing the notified chemical is applied are expected to be recycled. During the de-inking process, the UV-cured ink containing the notified chemical is unlikely to be released into the supernatant waters. Based on its anionic and surfactant properties, the majority of the cured ink containing the notified chemical is expected to adsorb to sludge and sediment and eventually disposed of to landfill or re-used for soil remediation. In landfill and in surface waters, the notified chemical is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with half of the paper products containing the notified chemical undergoing recycling (i.e. 2.5% of the import volume), and the notified chemical to be released into sewers with no removal during recycling or STP processes. As the notified chemical bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	2.5%	
Annual quantity of chemical released to sewer	25	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.10	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.021	µg/L
PEC - Ocean:	0.002	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.02 µg/L may potentially result in a soil concentration of approximately 0.14 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 0.71 µg/kg and 1.42 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 = 1.514 mg/L	Toxic to fish
Daphnia Toxicity	48 h EC50 = 2.624 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	72 h E_rC50 = 9.791 mg/L	Toxic to algae

Based on the above acute ecotoxicological endpoints, the notified chemical is expected to be toxic to aquatic life. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is formally classified as 'Acute Category 2; Toxic to aquatic life'. Based on its lack of ready biodegradability and acute ecotoxicity, the notified chemical is formally classified as 'Chronic Category 2; Toxic to aquatic life with long lasting effects' under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most sensitive endpoint for fish. A safety factor of 100 was used given acute ecotoxicological endpoints are available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, 96 h)	1.514	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	15.14	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	0.021	15.14	**0.001**
Q – Ocean	0.002	15.14	**< 0.001**

The Risk Quotients for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Whilst the notified chemical is not expected to be biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume, and assessed use pattern in printing ink, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: National Institute of Environmental Research Notification No. 2006-29 'Regulations Regarding the Designation of Chemical Hazard Testing Institutes', Annex 5 Test Guidelines for Chemicals, Chapter 4, Clause 15 'Acute Oral Toxicity Study (Toxicity Classification System) December 19, 2006).

Species/Strain: Rat [Crl:CD(SD)]

Vehicle: None

Remarks - Method: The notified chemical was orally administered once to a group of 3 SD female rats at each dose levels of 300, 300, 2000 and 2,000 mg/kg in 1st, 2nd, 3rd and 4th steps. Mortality, clinical signs, body weight and gross pathological changes were examined for 15 days after administration.

RESULTS

Main Study

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3F	300	None
2	3F	300	None
3	3F	2,000	None
4	3F	2,000	None

Discriminating Dose: 2,000 mg/kg bw

Signs of Toxicity: None

Effects in Organs: None

Remarks - Results: There were no test chemical-related deaths, body weight and gross pathological changes during the study phase. During the first 2 days of the experiment in 3rd and 4th steps at dose level of 2,000 mg/kg, prone position, lateral position, subdued behaviour, irregular respiration and lacrimation were observed.

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: KIT (2008a)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100
E. coli: WP2uvrA

Metabolic Activation System: S9 from Aroclor 1254 induced rat liver

Concentration Range in Main Test: a) With metabolic activation: 156.3–5,000 µg/plate
b) Without metabolic activation: 156.3–5,000 µg/plate

Vehicle: DMSO

Remarks - Method: No significant deviations from the OECD guidelines. There was an additional confirmatory test (Test 2) with exactly same experimental conditions to main test (Test 1).
Positive controls:

With metabolic activation: 2-aminoanthracene (all strains)
Without metabolic activation: 2-nitrofluorene (TA98), sodium azide (TA100, TA1535), 9-aminoacridine (TA1537), 2–amonofluorene (WP2uvrA)

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	>5,000	5,000	negative
Test 2	-	>5,000	-	negative
Present				
Test 1	-	>5,000	5,000	negative
Test 2	-	>5,000	-	negative

Remarks - Results: No signs of toxicity were noted at any dose level. Precipitation was observed in 5,000 μg/plate concentration in the main study, which according to the study conductors, did not affect colony count. The number of revertant colonies in the vehicle-treated control was within the normal range, and the positive controls were all mutagenic in their appropriate tester strain, confirming the validity of the test.

CONCLUSION: The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Medvill (2008a)

B.3. Genotoxicity – *in vitro*

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 473 In vitro Mammalian Chromosome Aberration Test

Species/Strain: Chinese Hamster Lung cells

Cell Type/Cell Line: CHL/IU cells Passage No. 20, 29, 34

Metabolic Activation System: DMSO

Vehicle: The notified chemical was tested in two independent experiments, both with and without metabolic activation (S9 mix), obtained from rat liver previously treated with Arcolor 1254. The first experiment was a preliminary test where the maximum density was determined for setting up the main experiment. There were two additional continuous and confirmatory experiments conducted with continuous exposure to the notified chemical in absence and presence of metabolic activation. For 'without S9 mix' media, Mitomycin C (MMC) was added as positive control, whereas cyclophosphamide (CP) was added in 'with S9 mix' media for the same purpose.

Remarks - Method

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time (media without test substance)*
Absent			
Test 1	5*, 10*, 20*, MMC-0.2*	6	18
Test 2 (continuous)	2.5*, 5*, 10*, MMC-0.2*	24	0
Present			
Test 1	32.5*, 65*, 130*, CP-5*	6	18
Test 2 (confirmatory)	110*, 120*, 130*, CP-5*	24	0

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	>20	–	Negative
Test 2	>10	–	Negative
Present			
Test 1	>130	–	Negative
Test 2	>130	–	Negative

Remarks - Results

The notified chemical induced cytotoxicity to CHL/IU cells both in the presence and in absence of S9 mix. In test 1 (with S9) structural abnormalities frequency was increased statistically in high concentrations. There were also inconsistencies in cell viability and chromosomal aberration results. To check the reliability of this finding, a confirmatory test was performed. It was observed that the test substance induces a slight but statistically significant increase in frequency of cells with structural chromosome aberrations.

In absence of S9 mix, no statistically significant increase of chromosomal aberration to CHL/IU cells was observed in short or long exposure to the notified chemical.

Metaphase analysis data did not indicate any major change in chromatid/chromosome break, exchange or gap in any condition.

CONCLUSION

The notified chemical was clastogenic to CHL/IU cells treated *in vitro* under the conditions of the test (in presence of S9 mix at the highest dose).

TEST FACILITY

Medvill (2008b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks - Method	The test was conducted in accordance with the test guideline above. No significant deviation in protocol was reported.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	59.3
14	5.2	14	70.1
28	1.7	28	73.9

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 14 days (70.1%) and reached 73.9% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The test substance attained 1.7% degradation by 28 days. Therefore, the test substance is not considered to be readily biodegradable according to the OECD (301 C) guideline. Conclusion: The notified chemical is not readily biodegradable.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	KIT (2008b)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static.
Species	*Oryzias latipes* (ricefish)
Exposure Period	96 hours
Auxiliary Solvent	Tween® 80
Water Hardness	96.34 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UVD
Remarks – Method	A stock solution was prepared by weighing out 1.0265 g test substance, and then made up to 100 mL with Tween® 80: ground water (1:99, w/v) to give 10,000 mg/L. The stock solution was filtered through 0.45 µm PTFE membrane filter. The definitive test was conducted at nominal concentrations of 0.95, 1.53, 2.44, 3.91, 6.25, and 10.0 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (%)*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control	Control	10	0	0	0	0
Solvent control	Solvent control	10	0	0	0	0
0.95	0.81	10	0	0	0	0
1.53	1.18	10	0	10	20	20
2.44	1.94	10	0	60	80	90
3.91	3.04	10	100	100	100	100
6.25	4.36	10	100	100	100	100
10.00	7.64	10	100	100	100	100

LC50	1.514 mg/L (95% CI 1.285-1.809 mg/L) at 96 hours.
NOEC	0.86 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 96 h test period. The actual concentrations of the test substance were measured at 0, 48, and 96 hours during the 96 h test period. The 96 h LC50 and NOEC for fish were determined to be 1.514 mg/L and 0.86 mg/L, respectively, based on measured concentrations.

CONCLUSION The notified chemical is considered to be toxic to fish.

TEST FACILITY KTR (2008a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 *Daphnia sp.* Acute Immobilisation Test and Reproduction Test – Static.

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Tween® 80
Water Hardness	204.29 mg $CaCO_3$/L
Analytical Monitoring	HPLC-UVD
Remarks - Method	A stock solution was prepared by weighing out 1.0265 g test substance, and then made up to 100 mL with Tween® 80: ground water (1:99, w/v) to give 10,000 mg/L. The stock solution was filtered through 0.45 µm PTFE membrane filter. The definitive test was conducted at nominal concentrations of 0.95, 1.53, 2.44, 3.91, 6.25, and 10.0 mg/L of the test substance. A total of 20 daphnids were used. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Cumulative Immobilised (%)*	
Nominal	*Actual*		*24 h*	*48 h*
Control	Control	20	0	0
Solvent control	Solvent control	20	0	0
0.95	0.85	20	0	0
1.53	1.25	20	0	0
2.44	1.90	20	5	20
3.91	3.05	20	30	70
6.25	4.69	20	75	100
10.00	8.25	20	95	100

EL50 2.624 mg/L (95% CI 2.313-2.978 mg/L) at 48 hours

NOEC	1.30 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The actual concentrations of the test substance were measured at 0 and 48 hours during the 48 h test period. The 48 h EC50 and NOEC for *Daphnia* were determined to be 2.624 mg/L and 1.30 mg/L, respectively, based on measured concentrations.
CONCLUSION	The notified chemical is considered to be toxic to aquatic invertebrates.
TEST FACILITY	KTR (2008b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 0.50-48.83 mg/L Actual: 0.42-41.00 mg/L
Auxiliary Solvent	Tween® 80
Water Hardness	Not reported
Analytical Monitoring	HPLC-UVD
Remarks - Method	A stock solution was prepared by weighing out 1.0265 g test substance, and then made up to 100 mL with TweenⓇ 80: ground water (1:99, w/v) to give 10,000 mg/L. The stock solution was filtered through 0.45 µm PTFE membrane filter. The definitive test was conducted at nominal concentrations of 0.50, 1.25, 3.13, 7.81, 19.53, and 48.83 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

Biomass		*Growth*	
E_bC50	*NOE_bC*	*E_rC50*	*NOE_rC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
4.097 (95% CI 3.552-4.730)	1.02	9.791 (95% CI 8.375-11.548)	2.38

Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 72 h test period. The actual concentrations of the test substance were at 0 and 72 hours within the 72 h test period. The 72 h E_rC50 and E_bC50 were determined to be 9.791 mg/L and 4.097 mg/L, respectively, based on the measured concentrations. The 72 h NOEC was determined to be and 2.38 mg/L.
CONCLUSION	The notified chemical is considered to be toxic to algae.
TEST FACILITY	KTR (2008c)

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