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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

MIRAMER M1086

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.

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

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1522	MacDermid Printing Solutions LLC	MIRAMER M1086	ND*	≤ 10 tonnes per annum	Component of UV curable printing plates

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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 Aquatic Toxicity (Category 1)	H400 – Very toxic to aquatic life
Chronic Aquatic Toxicity (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 chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment provided that the notified chemical is not released to sewer or surface waters.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Due to the ecotoxicity of the notified chemical, the notifier should consider their obligations under the Australian Dangerous Goods Code.

(Material) Safety Data Sheet

- The (M)SDS of the notified chemical should reflect the absence of data for reproductive toxicity.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Use closed and automated systems, where possible
  - Provide adequate local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical :
  - Avoid contact with skin
  - Avoid inhalation

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Impervious gloves
  - Protective clothing/coveralls
  - Respiratory protection, if inhalation exposure may occur

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Environment

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

Disposal

- Where reuse or recycling are unavailable or impracticable, dispose of the chemical in an environmentally sound manner in accordance with relevant Commonwealth, State, Territory and local government legislation.

Storage

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

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- further information becomes available on the repeated dose, reproductive or developmental effects of the notified chemical;
- the notified chemical, reformulated mixtures or waste water associated with equipment and container cleaning operations are to be released, directly or indirectly, to sewers or to surface waters.

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

APPLICANT(S)
MacDermid Printing Solutions LLC (ABN: 95 066 897 363)
29 Dennis St
Campbellfield, VIC 3061

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, residual impurities, additives/adjuvants, use details and details of analogue chemicals.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints (exception: water solubility and hydrolysis as a function of pH), acute dermal toxicity, acute inhalation toxicity and repeated dose toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
USA, Korea.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MIRAMER M1086

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference IR, TGA, DSC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid

Property	Value	Data Source/Justification
Boiling Point	340.2 ± 17 °C at 101.3 kPa	(M)SDS
Density	0.946 ± 0.06 kg/m^3 at 25 °C	(M)SDS
Vapour Pressure	1.16 x 10^{-5} kPa at 25 °C	(M)SDS
Water Solubility	0.192 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	$t_{½}$ = 18.7 – 115.5 days at 20 °C, pH 4 – 9	Measured
Partition Coefficient (n-octanol/water)	log Pow = 3.54	Calculated (KOWWIN v1.68, USEPA, 2011)
Adsorption/Desorption	log K_{oc} = 2.64 at 25 °C	Calculated by Kow method (KOCWIN v2.00, USEPA, 2011)
Dissociation Constant	Not determined	No dissociable functionality

Flash Point	110 °C	(M)SDS
Autoignition Temperature	> 400 °C	(M)SDS
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

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

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

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as the chemical itself (100%).

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 10	≤ 10	≤ 10	≤ 10	≤ 10

PORT OF ENTRY
Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
MacDermid Printing Solutions LLC.

TRANSPORTATION AND PACKAGING
The notified chemical (at 100% concentration) will be imported by sea in 200 kg steel drums. These drums will be transported by road to the notifier's warehouse where it will be stored on pallets. The reformulated products containing 9% of the notified chemical will be packaged into 1,000 L intermediate bulk containers (IBCs) or 20 L steel pails and supplied by road to the end users.

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

OPERATION DESCRIPTION
Reformulation/Repackaging
The notified chemical will be transferred to the mixing area and then pumped into a closed mixing kettle by an operator wearing appropriate personal protective equipment (PPE) using a spear pump, with appropriate exhaust ventilation. The closed mixing kettle will contain 9% of the notified chemical and other ingredients to manufacture the reformulated products in 3,000 kg batches. After 2 hours of mixing, small samples will be taken for quality assessment purposes by the process chemist wearing appropriate PPE for testing in a laboratory. Once the formulated products containing the notified chemical have been manufactured and tested, they will be packed into 1,000 L IBCs or 20 L pails using a pump under appropriate exhaust ventilation.

End-User Applications
Formulated products containing 9% notified chemical will be supplied to companies for the manufacture of elastomeric printing plates for applications such as printing designs onto corrugated cardboard cartons. The companies will transfer the formulated products through a closed automated system to a plate making machine,

where trays containing negative artwork and the photopolymer will be exposed to UV light to produce a positive elastomeric plate. The resulting printing plates will be used in printing processes to produce images on cardboard cartons.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage workers	1	12
Manufacturing operators	1	80
Cleaning and maintenance workers	0.5	80
Formulation Quality Inspector	0.5	80
End user: Printing plate operators	0.5	60

EXPOSURE DETAILS

Transport and Storage

The notified chemical will be imported at 100% concentration. Exposure of transport and storage workers to the notified chemical is not expected, except in the event of an accidental rupture of containers.

Reformulation

At the reformulation site, the notified chemical in liquid form will be transferred to a closed mixing kettle. Dermal, ocular and perhaps inhalation exposure to the notified chemical at 100% may occur during the transfer, removal and testing of the chemical. Dermal, ocular and inhalation exposure to the notified chemical at 9% concentration may also occur during reformulation, testing, packaging and transfer of the reformulated mixtures, and during general cleaning and maintenance of the reformulation equipment. Exposure to the notified chemical would be reduced by use of the engineering controls and PPE.

End-User Application

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

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

6.1.2. Public Exposure

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

6.2. Human Health Effects Assessment

The 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
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration	non genotoxic

Toxicokinetics, metabolism and distribution.
Based on the water solubility (0.192 g/L at 20 °C), the partition coefficient (calculated; log Pow = 3.54) and the low molecular weight (< 500 Da) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur. Absorption across the respiratory tract may also occur.

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

Acute toxicity.
The notified chemical was found to be of low acute toxicity via the oral route in a study in rats.

No acute dermal and inhalation toxicity data on the notified chemical were provided by the notifier. While information is available to suggest that low molecular weight chemicals containing acrylate groups are, in general, of low acute toxicity (which is supported by the results of the abovementioned acute oral toxicity study), there is uncertainty associated with the potential acute toxicity of the notified chemical as it also contains a glycol component.

Irritation and sensitisation.
In a skin irritation study in rabbits, slight to well-defined erythema (and/or keratinocyte formation) was noted in all animals, with the effects resolving by day 10. In an eye irritation study in rabbits, conjunctival redness, chemosis and discharge were seen in all animals, with no symptoms of eye irritation remaining by the 48 hour observation. Based on these observations, the notified chemical was not considered to meet the criteria for classification as a skin or eye irritant.

A Buehler test was conducted to determine the skin sensitisation potential of the notified chemical in guinea pigs (12.5% induction concentration; 6.25% challenge concentration). In the induction phase, colouring of the skin and/or crust formation was observed on the application site in 13 animals, following treatment with the test substance. During the challenge phase, no skin reactions were observed. The notified chemical was not considered to be a skin sensitiser under the conditions of the test. However, it is noted that acrylates are potential sensitisers (US EPA, 2010).

Repeated dose toxicity.
No data on the repeat dose toxicity were provided for the notified chemical. Following sub-chronic exposures to atmospheres of excessive concentrations of acrylates and/or methacrylates, pulmonary congestion or haemorrhage and cloudy swelling and organ weight changes of the liver and kidney have been reported (Patty's Toxicology, 2012). In addition, studies with rats on acrylate-containing analogues of the notified chemicals (identities exempt from publication) have shown after repeated inhalation exposure, irritating effects to nasal and respiratory mucosa and the eyes, and/or degeneration of the olfactory epithelium. In addition, fetotoxic effects have been noted at maternally toxic concentrations in developmental toxicity studies.

The abovementioned analogues of the notified chemicals are classified (HSIS) as being irritating to the skin, eyes and/or respiratory system and/or as causing sensitisation by skin contact. Given that the available data on the notified chemical indicates that it would not be classified for skin or eye irritation or skin sensitisation, the

relevance of the abovementioned effects to the notified chemical, particularly with respect to respiratory irritation, is uncertain. However, systemic toxicity has also been associated with short-chain ethylene glycol ethers and they are known to be developmental and reproductive toxicants (US EPA, 2010). Therefore, in the absence of data on the notified chemical the potential for systemic effects (including reproductive and/or developmental effects) following exposure to the notified chemical cannot be ruled out.

Mutagenicity/Genotoxicity.
The notified chemical was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an in vitro mammalian chromosome aberration test.

Health hazard classification
Based on the limited available information, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, 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 notified chemical has limited available toxicological information and there is particular uncertainty about the potential chronic health effects of the notified chemical, if repeated exposure occurs.

Workers with the greatest potential for dermal, ocular and inhalation exposure will be those handling the notified chemical (100%) at the reformulation site, particularly during the transfer and mixing processes. Both workers handling the reformulated mixture at the reformulation sites and workers who will use the reformulated mixture to make elastomeric printing plates at the end-use sites, may also have dermal, ocular and inhalation exposure to the notified chemical at 9% concentration. In the plate-making process, the multiple steps involved, high viscosity of the formulated mixture and the need for manual transfer of partially completed plates will increase the potential for drips and spills, contaminating the surfaces and the atmosphere with the formulated mixture containing the notified chemical at 9% concentration. At both formulation and end-use sites, workers carrying out cleaning of equipment activities, will also be potentially exposed.

The use of automated equipment, closed processes and local exhaust ventilation during reformulation and elastomeric printing plates manufacturing processes would reduce the risk to workers. Safe work practices such as cleaning up any spills promptly and isolation of contaminated clothing, wash water, cleaning cloths and surfaces would assist in safe handling of the notified chemical. Given the uncertainties related to the hazard profile of the notified chemical, particularly following repeated exposure, PPE, such as impervious gloves, eye protection, protective clothing and, where necessary, respiratory protection should be used if exposure is possible.

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

Under the conditions of the occupational settings described, with engineering and PPE controls in place, the notified chemical is not considered to pose an unreasonable risk to the health of workers

6.3.2. Public Health

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

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

RELEASE OF CHEMICAL FROM USE

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

RELEASE OF CHEMICAL FROM DISPOSAL

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

7.1.2. Environmental Fate

The notified chemical will be UV-cured (chemically reacted) to form inert elastomeric printing plates and is not expected to be bioavailable. The majority of the cured notified chemical is expected to be disposed of to landfill where it will degrade by biotic and abiotic processes to form water and oxides of carbon. Whilst the notified chemical is not readily biodegradable, it has potential for biodegradation based on the results of a biodegradation study. It is also likely to hydrolyse under ambient environmental conditions (pH 4 – 9) based on the results of a hydrolysis study. For the details of the environmental fate studies please refer to Appendices A and C.

The notified chemical has a low vapour pressure and is not expected to readily volatilise. Therefore, any of the notified chemical that is released to the environment is not expected to volatilise to the atmosphere. The notified chemical is not expected to be released to sewers or aquatic environments. However, in the unlikely case whereby the notified chemical is released to waste waters, it is expected to be partially removed from effluent by sorption to sediment where it will degrade by biotic and abiotic processes. The predicted n-octanol/water partition coefficient (log Pow = 3.54) indicates the notified chemical is not expected to have a potential for bioaccumulation.

7.1.3. Predicted Environmental Concentration (PEC)

Predicted environmental concentrations (PECs) for riverine and marine environments have been calculated assuming that up to 2% of notified chemical may accidentally be released to sewer. These releases may occur from equipment cleaning or spills at a reformulation site situated in a typical metropolitan area. Based on SimpleTreat calculations (European Commission, 2003) it was assumed that 52% of the notified chemical would be removed from effluent in sewage treatment plants (STPs) due to partitioning to sludge (19%) and inherent degradation (33%). It was also assumed that release of the notified chemical occurred over 260 days per annum, corresponding to the number of working days per annum.

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:	0.769	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	358	ML/day
Removal within STP	52%	Mitigation
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.03	µg/L
PEC - Ocean:	0.10	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 4.08 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 0.027 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 0.135 mg/kg and 0.27 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 1.03 µg/L may potentially result in a soil concentration of approximately 6.876 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 34.38 µg/kg and 68.76 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 = 0.052 mg/L	Very toxic to fish
Daphnia Toxicity	48 h EC50 = 0.47 mg/L	Very toxic to aquatic invertebrates
Algal Toxicity	72 h EC50 = 2.12 mg/L	Toxic to algae

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is considered to be very toxic to fish and aquatic invertebrates, and toxic to algae. Based on the measured acute toxicity to aquatic organisms, the notified chemical is formally classified under the GHS as “Acute category 1; Very toxic to aquatic life”. On the basis of the acute toxicity and the lack of ready biodegradability, the notified chemical is classified 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) was calculated based on the endpoint of the most sensitive species (fish) and an assessment factor of 100. An assessment factor of 100 was considered appropriate as endpoints from species representing three trophic levels were available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish).	0.052	mg/L
Assessment Factor	100	
PNEC:	0.52	µg/L

7.3. Environmental Risk Assessment

The risk quotient for the riverine and marine environment was calculated and presented in the table below:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	1.03	0.52	1.983

Q - Ocean:	0.10	0.52	0.198

The risk quotient (Q = PEC/PNEC) for riverine exposure was calculated to be > 1 based on the above calculated PEC and PNEC values. However, the notifier states that the notified chemical potentially released due to spills will be collected and disposed of by a licensed chemical waste disposal company. Therefore, as wastes are expected to be collected and disposed of to landfill, and there is no expected aquatic exposure, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment based on its reported use pattern. To ensure the notified chemical does not pose an unreasonable risk to the environment, all measures should be taken to ensure the notified chemical is not released to sewers or surface waters.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0.192 g/L at 20 °C

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method. The soluble amount was determined by a total organic carbon analyser.
Test Facility KOPTRI (2013)

Hydrolysis as a Function of pH $t_{½}$ = 18.7 – 115.5 days at 20 °C, pH 4 – 9

Method OECD TG 111 Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ (days)*
4	20	115.5
7	20	18.7
9	20	33.0

Remarks A preliminary test indicated > 10% degradation after 5 days for the test substance at 50 °C at pH 4, 7 and 9. Tier 2 testing was conducted with three different buffer solutions (pH 4.0, 7.0 and 9.0) at three temperature conditions (20 °C, 30 °C and 50 °C). Test substance quantification was undertaken by GC analysis.
Test Facility KIT (2014)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Corn oil
- Remarks - Method: No significant protocol deviations.
  GLP Certificate.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	300	0/3
2	3 F	300	0/3
3	3 F	2,000	0/3
4	3 F	2,000	0/3

- LD50: > 2,000 mg/kg bw
- Signs of Toxicity: No clinical signs were observed.
- Effects in Organs: No abnormalities were noted at necroscopy.
- Remarks - Results: No mortalities occurred during the study period.
  Over the entirety of the test period, all animals showed gains in body weight.

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

TEST FACILITY: KTR (2013a)

B.2. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD: Similar to OECD TG 404 Acute Dermal Irritation/Corrosion.
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 M
- Vehicle: Used as supplied
- Observation Period: 10 days
- Type of Dressing: Semi-occlusive.
- Remarks - Method: No significant protocol deviations.
  GLP Certificate.

  The first animal was initially exposed to the test substance for 3 minutes, then 1 hour and then for 4 hours, using 3 different patches and previously untreated test sites.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	1	1	2	< 10 days	0
Oedema	0	0	0	0	-	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

- Remarks - Results: Well defined erythema was observed in all three animals at the first

observation 1 hour post application. One animal recovered from this irritation by the 24 hour observation. The other two animals showed very slight erythema up to day 8 and 9. These two animals also showed keratinocytes formation from day 4. Signs had resolved in all animals by day 10. No oedema was noted in any test animal during the test period.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY KTR (2013b)

B.3. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 4
Observation Period 72 hours
Remarks - Method No significant protocol deviations.
GLP Certificate.

RESULTS

Lesion	*Mean Score**				*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4			
Conjunctiva: redness	0.33	0.33	0.33	0.33	2	< 48 hours	0
Conjunctiva: chemosis	0	0.33	0	0	2	< 48 hours	0
Conjunctiva: discharge	0	0	0	0	2	< 24 hours	0
Corneal opacity	0	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	0	-	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animals.

Remarks - Results Conjunctival redness (grade 2), chemosis (grades 1-2) and discharge (grades 1-2) were seen in all animals at the observation 1 hour post instillation. Conjunctival redness (grade 1) remained in all animals and chemosis (grade 1) remained in one animal at the 24 hour observation. No symptoms of eye irritation remained by the 48 hour observation.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY KTR (2013c)

B.4. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – Buehler test.
Species/Strain Guinea pig/CrlOri:HA
PRELIMINARY STUDY Minimally irritating Concentration:
topical: 12.5%
MAIN STUDY
Number of Animals Test Group: 20 F Control Group: 10 F (positive) + 10 F (negative)
INDUCTION PHASE Induction Concentration: topical: 12.5%
Signs of Irritation Colouring of the skin and/or crust formation were observed on the application site in 13 animals treated with the test substance (days 7-22).
CHALLENGE PHASE topical: 6.25%
Remarks - Method The test substance was prepared in ethanol (80%) and acetone, at induction and challenge, respectively.

A preliminary test was conducted at 12.5-100% concentration (2 animals/concentration), with mild-moderate responses reported at all concentrations.

Negative control: 80% ethanol
Positive control: 1,chloro-2,4-dinitrobenzene (1% w/v in corn oil)

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions at Challenge:*	
		24 h	*48 h*
Test Group	6.25%	0/20	0/20
Control Group			
Positive	1%	10/10	6/10
Negative	6.25%	0/10	0/10

Remarks - Results: During the challenge phase, no skin reactions were observed. The positive and negative controls elicited predictable results that validated the test system.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: KTR (2012)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE: Notified chemical

METHOD: Similar to OECD TG 471 Bacterial Reverse Mutation Test.
Pre-incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA	
Metabolic Activation System	S9 fraction from Aroclor-1254 induced rat liver	
Concentration Range in Range-finding Test	With and without metabolic activation:	50 – 5,000 µg/plate
Concentration Range in Main Test	With and without metabolic activation:	6.25 – 100 µg/plate
Vehicle	Dimethyl sulfoxide (DMSO)	
Remarks - Method	No significant protocol deviations. GLP Certificate.	

The results from the range finding test are reported as Test 1.

Positive control tests were run in parallel to the main study (controls included sodium azide, 9-aminoacridine and 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide in the absence of metabolic activation and 2-aminoanthracene in the presence of metabolic activation).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1	≥ 100	> 5000	negative
Test 2	≥ 100	> 100	negative
Present			
Test 1	≥ 500	> 5000	negative

Test 2	> 100	> 100	negative

Remarks - Results
There was no significant increase in the number of revertant colonies at any concentration in any of the strains for the test substance either in the presence or absence of S9 mix, in comparison to the negative control.

Results for the positive controls showed marked increases in the number of revertant colonies compared to the negative control.

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

TEST FACILITY
KTR (2013d)

B.6. Genotoxicity – in vitro

TEST SUBSTANCE
Notified chemical

METHOD
Similar to OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain	Hamster/Chinese
Cell Type/Cell Line	Lung
Metabolic Activation System	S9 fraction from Aroclor-1254 induced rat liver
Vehicle	Dimethyl sulfoxide (DMSO)
Remarks - Method	GLP Certificate. A preliminary assay was performed: tested both with (6 hour exposure) and without (6 and 24 hour exposures) metabolic activation at concentrations up to 1,000 µM. Positive control tests were run in parallel to the main study (mitomycin C and cyclophosphamide monohydrate).

Metabolic Activation	*Test Substance Concentration (µM)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	16.3*, 32.5*, 65*, 130	6 hours	24 hours
Test 2	15*, 30*, 60*, 120	24 hours	24 hours
Present			
Test 1	156.3*, 312.5*, 625*, 1250*	6 hours	24 hours

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µM) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 156	> 65	> 130	negative
Test 2	≥ 156	> 60	> 120	negative
Present				
Test 1	≥ 1,250	> 1,250	> 1,250	negative
Test 2				

Remarks - Results
The test substance showed no statistically significant increase in aberration frequencies of cells either in the presence or absence of metabolic activation.

Results for the positive controls compared to the negative control confirmed the validity of the test system.

CONCLUSION	The notified chemical was not clastogenic to Chinese Hamster Lung cells treated in vitro under the conditions of the test.
TEST FACILITY	KTR (2013e)

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	Not reported
Analytical Monitoring	Biological oxygen demand (BOD) meter
Remarks - Method	Conducted in accordance with the test guidelines above, and according to GLP principles.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation (BOD)*	*Day*	*% Degradation (BOD)*
7	10.2	7	65.2
14	18.7	14	72.7
28	26.5	28	83.1

Remarks - Results	All validity criteria were satisfied. The reference compound (aniline) attained > 40% and > 60% biodegradation by day 7 and 14, respectively, thereby indicating the suitability of the microorganisms for the test.
CONCLUSION	The notified chemical is not readily biodegradable.
TEST FACILITY	KIT (2012)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static.
Species	Ricefish (*Oryzias latipes*)
Exposure Period	96 hours
Auxiliary Solvent	Triethylene glycol
Water Hardness	61 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	Conducted according to the guidelines above, in accordance with GLP principles. The test substance was identified as a poorly water soluble substance that was unstable in dilution water. Therefore, this study was conducted using the organic solvent triethylene glycol to result in test substance solutions that were found to be stable over 24 hours. Stock solution was prepared with dilution water containing 100 mg triethylene glycol/L. The test solutions were renewed every 24 hours. A control and solvent control (100 mg triethylene glycol/L) were run in parallel to the test solutions.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality (Cumulative)*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	10	0	0	0	0	0
Solvent control	-	10	0	0	0	0	0
1	0.0086	10	0	0	0	0	0
1.7	0.0136	10	0	0	0	0	0
3.1	0.0233	10	0	0	0	0	0
5.6	0.0389	10	0	0	0	0	0
10	0.0651	10	0	0	1	7	10

LC50	0.052 mg/L (95% CI: 0.048 – 0.057 mg/L) at 96 hours.
NOEC	0.0389 mg/L at 96 hours.
Remarks – Results	All validity criteria were met and no significant deviations to protocol were reported. The concentration of the test substance in the treatment solutions were analysed by HPLC. As the concentration of the test substance in several treatment groups exceeded ±20% of the nominal values, the test results were calculated on the geometric means of the measured test substance concentrations during the exposure period. Sub-lethal effects such as hypoactivity were noted in the highest test concentration at 48 h and 72 h.

CONCLUSION The notified chemical is very toxic to fish

TEST FACILITY Biotoxtech (2013a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Semi-static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Triethylene glycol
Water Hardness	Not reported
Analytical Monitoring	HPLC
Remarks - Method	Conducted according to the guidelines above, in accordance with GLP principles. The test substance was identified as a poorly water soluble substance that was unstable in dilution water. Therefore, this study was conducted using the organic solvent triethylene glycol to result in test substance solutions that were found to be stable over 24 hours. Stock solution was prepared with dilution water containing 100 mg triethylene glycol/L. The test solutions were renewed every 24 hours. A control and solvent control (100 mg triethylene glycol/L) were run in parallel to the test solutions.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
Solvent control	-	20	0	0
10	0.0917	20	0	0
17	0.141	20	0	0
31	0.248	20	0	0
56	0.455	20	2	9
100	0.789	20	17	20

EC50 0.47 mg/L (95% CI : 0.41 – 0.53 mg/L) at 48 hours

NOEC	0.247 mg/L at 48 hours
Remarks - Results	All validity criteria were met and no significant deviations to protocol were reported. The concentration of the test substance in the treatment solutions were analysed by HPLC. As the concentration of the test substance in several treatment groups exceeded ±20% of the nominal values, the test results were calculated on the geometric means of the measured test substance concentrations during the exposure period. Sublethal effects such as a decrease in attennae movement were observed in the two highest test concentrations.
CONCLUSION	The notified chemical is very toxic to aquatic invertebrates
TEST FACILITY	Biotoxtech (2013b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test – Static
Species	*Psuedokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 5, 11, 23, 48 and 100 mg/L Actual: 0.127, 0.245, 0.402, 1.21 and 2.45 mg/L
Auxiliary Solvent	Triethylene glycol
Water Hardness	Not reported
Analytical Monitoring	HPLC
Remarks - Method	Conducted according to the guidelines above, in accordance with GLP principles. The test substance was identified as a poorly water soluble substance that was unstable in dilution water. Therefore, this study was conducted using the organic solvent triethylene glycol to result in test substance solutions that were found to be stable over 24 hours. Stock solution was prepared with dilution water containing 100 mg triethylene glycol/L. A control and solvent control (100 mg triethylene glycol/L) were run in parallel to the test solutions.

RESULTS

Biomass		*Growth*	
EyC50 *mg/L at 72 h*	*NOEC* *mg/L*	*ErC50* *mg/L at 72 h*	*NOEC* *mg/L*
0.660 (95% CI: 0.606 – 0.720)	0.245	2.12 (95% CI: 1.87 – 2.45)	0.245

Remarks - Results	All validity criteria were met and no significant deviations to protocol were reported. The concentration of the test substance in the treatment solutions were analysed by HPLC. As the concentration of the test substance in several treatment groups exceeded ±20% of the nominal values, the test results were calculated on the geometric means of the measured test substance concentrations during the exposure period.
CONCLUSION	The notified chemical is toxic to alga
TEST FACILITY	Biotoxtech (2013c)

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