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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Urea, reaction products with ammonium hydroxide, *N*-cyanoguanidine and formaldehyde

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 Agriculture, Water and 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
STD/1697	Cintox Australia Pty Ltd	Urea, reaction products with ammonium hydroxide, *N*-cyanoguanidine and formaldehyde	ND*	≤ 500 tonnes per annum	Component of fertilisers applied to soil

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the notified chemical cannot be recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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 3	H402 - Harmful to aquatic life

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 in the aquatic environment, the low terrestrial hazard 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 safe work practices to minimise occupational exposure during handling of the notified chemical during mixing or final use:
  - Avoid contact with skin and eyes

- 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 during mixing or final use:
  - Impervious gloves
  - Protective clothing
  - Safety glasses or goggles

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

- A copy of the 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.

Emergency procedures

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

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.

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 a component of fertilisers applied to soil, 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.

Safety Data Sheet
The SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cintox Australia Pty Ltd (ABN: 63 122 874 613)
26 Male Street
BRIGHTON VIC 3186

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details exempt from publication include: other name, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, import volume and identity of analogue.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for freezing point, repeated dose toxicity, mutagenicity and genotoxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2018)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Pronitridine

CAS NUMBER
1373256-33-7

CHEMICAL NAME
Urea, reaction products with ammonium hydroxide, *N*-cyanoguanidine and formaldehyde

MOLECULAR WEIGHT
< 500 g/mol

ANALYTICAL DATA
Reference IR, GC-MS, UV-Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
15-25%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid

Property	*Value*	*Data Source/Justification*
Freezing Point	Not determined	Imported in solution
Boiling Point	90-94 °C at 101.3 kPa	Measured
Density	1,277.6 kg/m^3 at 20 °C	Measured
Viscosity	78.35 mPa·s at 20 °C 29.05 mPa·s at 40 °C	Measured
Vapour Pressure	1.38×10^{-4} Pa at 20 °C	Measured
Water Solubility	> 1,000 g/L at 20 °C	Measured

Property	*Value*	*Data Source/Justification*
Hydrolysis as a Function of pH	$t_{1/2}$ = 0.469 days	Measured for one component of the chemical
Partition Coefficient (n-octanol/water)	log Pow = -5.92 – -1.15	QSAR
Adsorption/Desorption	log K_{oc} = -0.88 – 0.25	QSAR
Dissociation Constant	pKa = 2.74 – 3.7	Measured
Flash Point	> 104 °C at 101.3 kPa	Measured
Flammability	Not determined	Not expected to be highly flammable based on flashed point
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Non-explosive	Measured
Stability	Stable at normal and elevated temperature	Measured
Oxidising Properties	Compatible with water, kerosene, monoammonium, zinc dust and phosphate Incompatible with potassium permanganate	Measured

DISCUSSION OF PROPERTIES
For 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.

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 in Australia. The notified chemical will be imported in a water-based formulation at ≤ 20% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤ 500	≤ 500	≤ 500	≤ 500	≤ 500

PORT OF ENTRY
Throughout Australia

TRANSPORTATION AND PACKAGING
Products containing the notified chemical at ≤ 20% concentration will be imported in 1,000 L IBC or 20,000 L isotainers and transported by road within Australia.

USE
The notified chemical will be used as a nitrification inhibitor and will be applied alongside fertilisers such as anhydrous ammonia gas, aqua ammonia, urea ammonium nitrate and other liquid ammoniacal or urea nitrogen fertilisers and liquid manure. The application will be to soil only prior to planting.

Use with anhydrous ammonia
The product containing the notified chemical will be applied to anhydrous ammonia at a rate of 21 L/metric tonne (1.33%). This is equivalent to 4.2 L/metric tonne (0.54%) of the notified chemical. The mixture will be applied to the soil at a rate of ≤ 6 L/hectare per application, with an anticipated rate of ≤ 15 L/hectare/year.

Use with liquid fertilisers
The product containing the notified chemical will be applied with liquid fertilisers (e.g. solution of urea ammonium nitrate) at a rate of 10.5 L/metric tonne (0.664%). This is equivalent to 2.1 L/metric tonne (0.27%) for the notified chemical. The mixture will be applied to the soil at a rate of ≤ 6 L/hectare per application, with an anticipated rate of ≤ 15 L/hectare/year.

OPERATION DESCRIPTION
Trained technicians will pump the imported product containing the notified chemical at ≤ 20% concentration into liquefied anhydrous ammonia or liquid fertiliser tanks at the distributors site or at farm. Farmworkers will be involved in any further mixing of the fertiliser mixture and its application to soil. When used with anhydrous ammonia, the final mixture will be applied by conventional ammonia injection equipment or downstream co-injection systems that place the mixture in close proximity to anhydrous ammonia. When used with liquid fertilisers, the final mixture will be applied by broadcast sprayer and side-dress (dribble band and knifed).

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	2	100
Container filling	2	100
End-users (contract applicator)	2	100
End-users (grower)	12	14

EXPOSURE DETAILS

Transport and storage
Transport and storage workers may come into contact with the notified chemical at ≤ 20% concentration only in the event of an unlikely accidental rupture of bags containing the notified chemical.

Mixing
Dermal, ocular and inhalation exposure of workers to the notified chemical at ≤ 20% concentration may occur during connection and disconnection of transfer lines and cleaning and maintenance of equipment. Exposure is expected to be limited through the use of control measures (such as bunded areas supplied with local and general ventilation) and personal protective equipment (PPE) such as coveralls, impervious gloves and safety glasses, as stated by the notifier.

Application to soil
Dermal, ocular and inhalation exposure of workers to the notified chemical at ≤ 20% concentration may occur during application to soil. Exposure is expected to be limited through the use of PPE such as coveralls, impervious gloves, safety glasses or masks, as stated by the notifier.

6.1.2. Public Exposure
Product containing the notified chemical will not be made available to the public. Application of products containing the notified chemical by soil injection or ground-boom application may lead to unintended bystander exposure via chemical spray drift. This may be in the form of a single random exposure or repeated exposure of residents who reside adjacent to areas being treated with the product. The concentration of the notified chemical in the spayed fertiliser solution is expected to be up to 0.8%.

As low energy/low pressure equipment are expected to be used in the boom spray, a low amount of fine spray particles will be generated during spraying. The end-users are expected to adhere to Australian Pesticides and Veterinary Medicines Authority's (APVMA) operating principals to prevent spray drifts (APVMA, 2008).

Indirect exposure to the notified chemical from residues in fruit and vegetables (in particular root vegetables) grown on treated soil is not expected to be significant based on the treatment being applied prior to planting, the low rate of application of the notified chemical, and the expected hydrolysis and biodegradation of the notified

chemical in soil. The product will degrade into well-characterized used agrochemicals and fertilizers (dicyanamide, urea, and urea formaldehyde fertilizers). Only simple molecules such as ammonia and nitrate are expected to be available for uptake into plants.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical and analogues are summarised in the following table. For details of the studies conducted on the notified chemical, refer to Appendix B. The notified chemical has structural moieties that include Analogue 1 and Analogue 2 (identities are exempt information). The notified chemical contains ≥ 75% impurities (identities are exempt information) that also have structural moieties that include Analogue 1 or Analogue 2. Therefore, the combined toxicity profile of the analogues is expected to be similar to that of the notified chemical.

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity
Acute dermal toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity
Acute inhalation toxicity – rat	LC50 > 5.111 mg/L/4 hour; low toxicity
Skin irritation – rabbit	slightly irritating
Eye irritation – rabbit	slightly irritating
Skin sensitisation – guinea pig maximisation assay	no evidence of sensitisation
Combined oral repeated dose toxicity study with the reproduction/developmental toxicity screening test – rat, ≥ 44 days*	maternal NOAEL = 1,000 mg/kg bw/day (males and females) reproduction/developmental NOAEL = 1,000 mg/kg bw/day
Oral repeated dose toxicity study – rat, 12 months^	NOAEL = 2,250 mg/kg bw/day
Oral repeated dose toxicity study – mouse, 12 months^	NOAEL = 6,750 mg/kg bw/day
Mutagenicity – bacterial reverse mutation*	non mutagenic
Mutagenicity – bacterial reverse mutation^	non mutagenic
Genotoxicity – *in vitro* chromosome aberration test*	non genotoxic
Carcinogenicity – rat, up to 2 years*	non carcinogenic
Carcinogenicity – rat, 12 months^	non carcinogenic
Carcinogenicity – rat, 12 months^	non carcinogenic

* The test substance was Analogue 1 (identity is exempt information)
^ The test substance was Analogue 2 (identity is exempt information)

Toxicokinetics
Based on the low molecular weight (< 500 g/mol), water solubility (> 1×10^3 g/L at 20 °C) of the notified chemical, there is potential for the chemical to cross biological membranes.

Acute Toxicity
The notified chemical was found to be of low acute toxicity via the oral, dermal and inhalation routes in studies conducted in rats.

Irritation and Sensitisation
The notified chemical was found to be slightly irritating to skin and eyes in studies conducted in rabbits. The slight irritation reactions were reversible within 48 hours after administration.

The notified chemical showed no evidence of sensitisation in a guinea pig maximisation test.

Repeated Dose Toxicity and Reproduction/Developmental Toxicity

No data were submitted for the notified chemical.

In a combined oral repeated dose toxicity study with the reproduction/developmental toxicity screening test, rats received Analogue 1 at doses of 40, 200, and 1,000 mg/kg bw/day for 44 days (males) or from 14 days before mating to day 3 of lactation (females) (OECD SIDS 2003). The NOAEL was considered to be 1,000 mg/kg/day for both sexes based on that the test substance had no effect on clinical signs, body weights and food consumption and there were no test-substance related necropsy and histopathological findings (OECD SIDS 2003). The NOAEL for reproductive and developmental toxicity was also considered to be 1,000 mg/kg bw/day as the test substance also had no effects on reproductive parameters (such as the mating index, fertility index, numbers of corpora lutea

or implantations, implantation index, delivery index, gestation index, gestation length, parturition or maternal behaviour) and neonates (such as the number of offspring or live offspring, sex ratio, live birth index, viability index or body weight) and there were no clinical signs or findings at necropsy for the offspring (OECD SIDS 2003).

In two 12-month chronic oral toxicity studies, Analogue 2 was administered to rats and mice via the diet at doses of 4,500, 9,000 or 45,000 ppm (approximately up to 2,250 mg/kg bw/day in rats and 6,750 mg/kg bw/day in mice respectively) with no treatment-related toxicity observed (Koch 2016a).

In a 28-day inhalation toxicity study, 10 male rats were exposed to a formulation aerosol containing 66-71% Analogue 2 at a 99.9 mg/m^3 concentration of the formulation (mean mass median aerodynamic diameter = 2.8 µm) for 6 hours/day for 5 days over the first 3 weeks and then for 4 days/week (Koch 2016a). Treatment-related adverse effects consisted of a slight increase in the relative lung organ weight and interstitial pneumonia in seven out of ten rats, with three of those seven also having minimal, multifocal interstitial fibrosis (Koch 2016a). No No-Observed-Adverse-Effect Concentration (NOAEC) was reported. Although multifocal interstitial fibrosis is a severe effect it was observed at ~99.9 mg/m^3 (aerosol). There is no information to indicate whether this effect is possible to occur at low doses.

Mutagenicity/Genotoxicity
No data were submitted for the notified chemical. Analogue 1 gave negative results in reverse mutation studies in bacteria and *in vitro* chromosomal aberration test with Chinese hamster lung cells, with and without metabolic activation (OECD SIDS 2003).

Analogue 2 was also negative in several reverse mutation studies in bacteria (Koch 2016a).

Carcinogenicity
No data were submitted for the notified chemical. A carcinogenicity study was conducted in rats fed diets containing Analogue 1 (identity is exempt information) at 2.5 and 5% (equivalent to 837.2 and 1,958.6 mg/kg bw/day respectively for males and 1,001.3 and 2,169.2 mg/kg bw/day respectively for females) for up to 2 years, finding no association of the test substance with an increased tumour incidence (OECD SIDS 2003).

In two 12-month carcinogenicity studies, Analogue 2 was administered to rats and mice via the diet at doses of 4,500, 9,000 or 45,000 ppm (approximately up to 2,250 mg/kg bw/day in rats and up to 6,750 mg/kg bw/day in mice respectively) with no treatment-related increase in carcinogenicity observed (Koch 2016a).

Health Hazard Classification
Based on the available information, the notified chemical cannot be recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation
Based on the available toxicological data, the notified chemical (15-25% purity) is expected to be of low hazard, presenting only as a slight skin and eye irritant. However, repeated dose inhalation toxicity data available is inconclusive.

6.3.1. Occupational Health and Safety
During mixing workers may be exposed to the notified chemical at ≤ 20% concentration. Exposure is expected to be minimised through the expected use of PPE such as coveralls, impervious gloves, safety glasses and respirator (if inhalation exposure is expected). The use of enclosed systems for mixing will also reduce worker exposure.

Although farmers may be exposed to the notified chemical when handling fertilisers, it is expected that the spray operations will be low energy/low pressure using ground boomer or injection application. Therefore, inhalation exposure to vapours, mists or aerosols during spray application is not likely to occur. Furthermore, the concentration of the notified chemical in spray solution is low (≤ 0.8%), therefore inhalation exposure to the notified chemical will not be significant.

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

6.3.2. Public Health

The products containing the notified chemical will not be made available to the public. Bystander risk is possible, but is expected to be limited based on the proposed use pattern. Potential routes of exposure for bystanders are dermal, inhalation and ocular during or immediately after a spraying event, while dermal exposure is the most likely route of exposure during re-entry situations. Workers adherence to good agricultural practice will minimise potential risks for the public during spray application.

Indirect exposure to the notified chemical from residues in fruit and vegetables (in particular root vegetables) grown on treated soil is not expected to be significant based on the treatment being applied prior to planting, low rates of application of the notified chemical, and expected hydrolysis and biodegradation of the notified chemical in soil. The product will degrade into well-characterized used agrochemicals and fertilizers (dicyanamide, urea, and urea formaldehyde fertilizers). Only simple molecules such as ammonia and nitrate would be available for uptake into plants.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical is not manufactured in Australia, and is imported as a part of a formulated product. Some release may occur during the repackaging of the formulated product. Accidental spills are expected to be contained and collected for and disposed of to landfill where recycling is not viable.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical will be applied to topsoil by soil injection with anhydrous ammonia or ground boom spraying, with liquid fertiliser. Both of these methods are unlikely to lead to significant spray drift of the notified chemical. Due to the low calculated log Koc (-0.88 to 0.25) and high water solubility, the notified chemical may become mobile in the environment and penetrate to groundwater or runoff into environmental waters.

RELEASE OF CHEMICAL FROM DISPOSAL

Any wastes of the notified chemical are expected to be collected for disposal by an approved waste management company. These wastes are expected to be disposed of in accordance with any applicable regulations and/or good farming practices.

7.1.2. Environmental Fate

A literature review of the environmental fate of the product containing the notified chemical and Analogue 1 was provided, indicated that the notified chemical is not considered readily biodegradable, but is expected to have a half-life of < 6 months in soil and sediment (Koch 2016b). Therefore, the notified chemical is not considered to be persistent. The notified chemical is not expected to bioaccumulate based on the calculated log Kow values between -5.92 and -1.15. The majority of the notified chemical is to be dispersed on to crop fields, with some left over chemical eventually being disposed of to landfill. In soil and landfill, the notified chemical is expected to slowly degrade via biotic and abiotic processes to form plant available nitrogen and oxides of carbon and nitrogen, and water.

7.1.3. Predicted Environmental Concentration (PEC)

The application rate for boom spray for the notified chemical is 20 g/ha (0.133% of 15 L/ha; see above). After application, rainfall events can lead to run-off of the notified chemical from soil to adjacent waterways. The method for estimating the concentration of the notified chemical in run-off is calculated based on the method used by the APVMA for pesticides (APVMA, 2016). The method uses an OECD based model (Probst et al., 2005), which considers the application rate, topography, in particular the slope of the field to which the chemical is applied, the magnitude of the rainfall and run-off events. A tier 1, worst-case scenario model was used that does not take into account the half-life or adsorption of the notified chemical.

The Predicted Environmental Concentration (PEC Run-off) for the notified chemical estimated to run-off is presented as follows**:**

Predicted Environmental Concentration (PEC Run-off)	
Precipitation mm	100
Run-off water mm	20
f1Slope	0.5
Heterogeneity factor	0.5
L% Run-off (percentage of applied pesticide)	5
Volume of run-off water m3 per hectare	200
Volume of run-off water L per hectare	200000
Edge of field Tier 1 Concentration µg/L	5

Additionally when sprayed the notified chemical may reach adjacent downwind waterways via spraydrift. A screening level calculation was used to determine the reasonable worst-case PEC (spray drift) for the notified chemical, assuming the direct overspray of 1 ha waterbody 15 cm deep (Lee-Steere, 2009):

$$\text{PEC(spray drift) (mg/L)} = (\text{Rate (kg)} \times 10^6 \text{ mg/kg} \times \text{no of applications})/(1.5 \times 10^6) \text{ L}$$

Where:
Application rate = 20 g/ha
Number of applications = 1

$$\text{PEC(spray drift) (mg/L)} = (0.02 \times 10^6 \text{ mg/kg} \times 1)/(1.5 \times 10^6 \text{ L}) = 0.013 \text{ mg/L} = 13 \text{ µg/L}.$$

Applications of the notified chemical via injection into soil are expected to be less susceptible to run-off and spraydrift.

A PEC (Soil) was not calculated as the notified chemical is not considered harmful to terrestrial organisms.

7.2. Environmental Effects Assessment

The endpoints for fish, daphnia and earthworms are based on Analogue 1 and are derived from study reviews conducted by the US EPA. The reviews on acute fish toxicity and acute daphnia toxicity are summarised in Appendix C. The earthworm review summary was not included in Appendix C, as raw data was not included in the review (US EPA 1987c). An endpoint value only was provided for chronic daphnia and chronic fish toxicity in the provided literature review (Koch 2016c). The endpoint value for algae is based on three studies on the notified chemical and is the most sensitive endpoint determined; see Appendix C for more details. In addition, a series of study reviews of avian toxicity completed by the US EPA were provided which indicated low avian toxicity (US EPA 1987d, US EPA 1987e, US EPA 1987f).

Endpoint	*Result*	*Assessment Conclusion*
Acute Fish Toxicity	EC50 > 100 mg/L	Analogue 1 is not acutely harmful to fish
Chronic Fish Toxicity	LC50 > 100 mg/L	Analogue 1 is not chronically harmful to fish
Acute Daphnia Toxicity	EC50 4230mg/L	Analogue 1 is not acutely harmful to invertebrates
Chronic Daphnia Toxicity	NOEC 25 mg/L	Analogue 1 is not chronically harmful to invertebrates
Algal Toxicity	ErC50 86 mg/L NOEC 50 mg/L	The notified chemical is harmful to algal growth
Earthworm Toxicity	EC50 > 3200 mg/kg	Analogue 1 is not harmful to earthworms

Based on the above ecotoxicological endpoints for the notified chemical, the notified chemical is expected to be harmful to algae. Therefore, the notified chemical is classified as "Acute Category 3 (H402): Harmful to aquatic life" according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009). Based on the three chronic ecotoxicological endpoints above, the notified chemical is not classified for long-term toxicity.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) for the notified chemical was calculated using the most sensitive endpoint available (Algae ErC50 = 86 mg/L). An assessment factor of 10 was used, as six endpoints (encompassing three trophic levels for both acute and chronic toxicity) are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ErC50 (Algae)	86	mg/L
Assessment Factor	10	
Mitigation Factor	1	
PNEC:	8600	µg/L

A PNEC was not calculated for terrestrial organisms, as the notified chemical is not considered harmful to earthworms (EC50 > 1000 mg/kg).

7.3. Environmental Risk Assessment

Risk Assessment	PEC (µg/L)	PNEC (µg/L)	Q
Q – Run off	5	8600	<< 0.01
Q – Spray Drift	13	8600	<< 0.01

The risk quotient (Q = PEC/PNEC) was calculated using the PEC of the notified chemical in an environmental waterbody after a worst-case run-off event and the PNEC of 8600 µg/L. This results in a Q value considerably less than 0.01, which indicates low risk to the aquatic environment. The risk quotient using the PEC (spray drift) was calculated which also resulted in a Q value considerably less than 0.01. A risk quotient was not calculated for soil, as the notified chemical is not expected to be harmful to terrestrial organisms.

On the basis of the PEC/PNEC ratio in the aquatic environment, the low terrestrial hazard and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point 90-94 °C at 101.3 kPa

Method OECD TG 103 Boiling Point
Remarks Determined using the Siwoloboff method
Test Facility JRF (2016a)

Density 1,277.6 kg/m^3 at 20 °C

Method US EPA OCSPP 830.7300 Density/Relative Density/Bulk Density
Remarks Determined using a pycnometer
Test Facility JRF (2016b)

Viscosity 78.35 mPa·s at 20 °C
29.05 mPa·s at 40 °C

Method OECD TG 114 Viscosity of Liquids
Remarks Determined using the rotational viscometer method
Test Facility JRF (2016c)

Vapour Pressure 1.38×10^{-4} Pa at 20 °C

Method OECD TG 104 Vapour Pressure
Remarks Determined using a thermogravimetric analyser
Test Facility JRF (2016d)

Water Solubility > 1,000 g/L at 30 °C (fully miscible)

Method In house method
Remarks 5 mL of the test substance was mixed with 50 mL of water in 250 mL beakers and solutions were observed for homogeneity. Test was carried out in triplicate. No separation or precipitation was observed.
Test Facility JRF (2016e)

Hydrolysis as a Function of pH

Method In house method

pH	*T (°C)*	*$t_{½}$ (days)*
9	30	0.469 for component 3

Remarks $t_{1/2}$ was only determined for component 3 of the notified chemical (identity is exempt information).
Test Facility Ricerca (2016a)

Dissociation Constant pKa = 2.74– 3.7

Method In house method
Remarks Test was completed using a potentiometric titration method.
Test Facility Pion (2016)

Flash Point > 104 °C at 101.3 kPa

Method EC Council Regulation No 440/2008 A.9 Flash Point
Remarks Closed cup
Test Facility JRF (2016f)

Explosive Properties Non-explosive

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	Determined using a differential scanning calorimeter. There was no exothermic decomposition up to 430°C.
Test Facility	JRF (2016g)

Stability Stable at normal and elevated temperatures

Method	US EPA OPPTS 830.6313 Stability to Normal and Elevated Temperature, Metals, and Metal Ions
Remarks	Stability was determined by comparison of the control samples to the elevated temperature samples of the test substance. Two of the four components of the product containing the notified chemical were stable over the 14 days of storage at approximately 54 °C. One component increased slightly while the remaining component decreased slightly.
Test Facility	Ricerca (2016b)

Oxidizing Properties Compatible with water, kerosene, monoammonium phosphate, and zinc dust
Incompatible with potassium permanganate

Method	US EPA OCSPP 830.6314 Oxidation/Reduction: Chemical Incompatibility
Remarks	Determined by visual observations of splattering, noxious fumes, evolution of gases and flames, or any temperature changes immediately and after 24 hours of contact.
Test Facility	JRF (2016h)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Notified chemical (15-25% purity)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/Wistar
Vehicle	None
Remarks – Method	No significant protocol deviations

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	2000	0/3
4	3 F	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	No signs of toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks – Results	Normal body weight gains were noted.
CONCLUSION	The test substance is of low acute toxicity via the oral route.
TEST FACILITY	JRF (2016i)

B.2. Acute Dermal Toxicity – Rat

TEST SUBSTANCE	Notified chemical (15-25% purity)
METHOD	OECD TG 402 Acute Dermal Toxicity
Species/Strain	Rat/Wistar
Vehicle	None
Type of dressing	Semi-occlusive
Remarks – Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 M/ 5 F	2000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity – Local	No local effects were noted.
Signs of Toxicity – Systemic	No test substance-related clinical signs were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks – Results	The test substance showed no effects on body weights of the animals.
CONCLUSION	The test substance is of low acute toxicity via the dermal route.
TEST FACILITY	JRF (2016j)

B.3. Acute Inhalation Toxicity – Rat

TEST SUBSTANCE	Notified chemical (15-25% purity)
METHOD	OECD TG 403 Acute Inhalation Toxicity
Species/Strain	Rat/Wistar
Vehicle	

Method of Exposure	Nose-only exposure
Exposure Period	4 hours
Physical Form	Liquid aerosol
Particle Size	3.25 ± 2.63 μm (average mass median aerodynamic diameter ± average geometric standard deviation)
Remarks – Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Concentration (mg/L)*		*Mortality*
		Nominal	*Actual*	
1	5 M/ 5 F	5.111	5.158	0/10

LC50	> 5.111 mg/L/4 hours
Signs of Toxicity	No test substance-related clinical signs were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks – Results	For male animals, decrease in mean body weight was noted on day 1 while increase was noted on days 3, 7 and 14. For female animals, a decrease in mean body weight was noted on days 1 and 3 while an increase was noted on days 7 and 14.

CONCLUSION The test substance is of low acute toxicity via inhalation.

TEST FACILITY JRF (2016k)

B.4. Skin Irritation – Rabbit

TEST SUBSTANCE Notified chemical (15-25% purity)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	No significant protocol deviations

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	0.33	0.33	0.33	1	< 48 hours	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	Very slight erythema was noted in all animals at the 1- and 24-hour observations and completely recovered by the 48-hour observation.

CONCLUSION The test substance is slightly irritating to the skin.

TEST FACILITY JRF (2016l)

B.5. Eye Irritation – Rabbit

TEST SUBSTANCE Notified Chemical (15-25% purity)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion

Species/Strain	Rabbit/New Zealand White

Number of Animals	3
Observation Period	72 hours
Remarks – Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva – Redness	0.3	0.3	0.3	1	< 48 hours	0
Conjunctiva – Chemosis	0	0	0	-	-	-
Corneal Opacity	0	0	0	-	-	-
Iridial Inflammation	0	0	0	-	-	-

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

Remarks – Results	Very slight conjunctival redness was noted in all animals at the 1- and 24-hour observations and completely recovered by the 48-hour observation. Iritis, chemosis and corneal opacity were not observed. No abnormalities were noted in the control eye of each rabbit.
CONCLUSION	The test substance is slightly irritating to the eye.
TEST FACILITY	JRF (2016m)

B.6. Skin Sensitisation – Guinea Pig Maximisation Test

TEST SUBSTANCE	Notified chemical (15-25% purity)
METHOD	OECD TG 406 Skin Sensitisation – Magnusson and Kligman
Species/Strain	Guinea pig/Hartley
PRELIMINARY STUDY	Maximum non-irritating concentration: Intradermal: 2.5% Topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 F Control Group: 5 F
Vehicle	Distilled water
Positive Control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde.
INDUCTION PHASE	Induction concentration: Intradermal: 5% (day 0) Topical: 100% (day 7)
Signs of Irritation	Well-defined erythema (in 10/10) and very slight oedema (in 8/10) to slight oedema (in 2/10) were observed on day 1 in treated animals the treatment group following intradermal injection (day 0). Very slight erythema (in 3/10) to well-defined erythema (in 7/10) and very slight oedema (in 8/10) to slight oedema (in 2/10) were observed on day 10 on the left flank of the treated animals following topical application on day 7. All control group animals showed no signs of skin irritation during the induction phase.
CHALLENGE PHASE	
Challenge	Topical: 100% (day 21)
Remarks – Method	No significant protocol deviations

RESULTS

Animal	*Challenge Concentration (%)*	*Number of Animals Showing Skin Reactions after Challenge*	
		24 h	*48 h*
Test Group	100	0	0
Control Group	100	0	0

Remarks – Results	Visual observation following challenge did not reveal any positive skin responses at the 24- and 48-hour observations for the treatment or control group. The validity of the test method was confirmed by the satisfactory result with the positive control conducted prior to the test.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.
TEST FACILITY	JRF (2016n)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute Toxicity to Fish

TEST SUBSTANCE	Analogue 1
METHOD	Methods for Acute toxicity tests with fish, macroinvertebrates and amphibians. EPA – 660/3-75-009
Species	*Onchorhynchus mykiss*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	115 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	This report is a Data Evaluation Record (DER) compiled by the US EPA. Water hardness was outside of the range prescribed in the test method (40-48 mg $CaCO_3$/L).

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality*
Nominal	*Actual*		*96 h*
1296	ND	10	0
2160	ND	10	1
3600	ND	10	0
6000	ND	10	1
10000	ND	10	9

LC50	7700 mg/L at 96 hours
Remarks – Results	The conclusion of the EPA was that this test could not be used to accurately determine the LC50 of the test substance due to the presence of undissolved test substance in all of the test samples. However, the notified chemical is readily soluble and is expected to have substantially dissolved in the test medium. Additionally all validity criteria were met. The dissolved oxygen concentration was > 6.8 mg/L (> 65% oxygen saturation in fresh water at 13°C; U.S. Geological Survey, 2011). The results from the control sample were not provided or discussed in the report.
CONCLUSION	In spite of some uncertainty due to some undissolved test substance, it can be reasonably concluded that the LC50 of the test substance is above 100 mg/L, and therefore the test substance is not considered harmful to fish.
TEST FACILITY	US EPA (1987a)

C.2.2. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static (1981)
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	210 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks – Method	This report is a Data Evaluation Record (DER) compiled by the US EPA. A 12 hr light/dark photoperiod was used instead of a 16 hr/ 8 hr light/ dark

photoperiod. This is not expected to have negatively influenced the study, as the altered photoperiod did not affect the control sample

RESULTS

Concentration (mg/L) Nominal	*Number of D. magna*	*Number Immobilised 48 h*
10	20	0
18	20	0
32	20	0
56	20	0
100	20	1
180	20	0
320	20	2
560	20	0
1000	20	1
1800	20	5
3200	20	4
5600	20	16
10,000	20	20

EC50 4230 mg/L at 48 hours
NOEC 56 mg/L at 48 hours

Remarks – Results This summary was based on a review completed by the US EPA and did not include the raw data for the control groups, however the DER indicates that there were no abnormalities.
The review indicates that the test met all validity criteria in the current OECD test guidelines. Dissolved oxygen was maintained at ≥ 6.3 mg/L. Additionally, pH was maintained between 7.8 and 8.3 and temperature was maintained at 19 ±1°C.

CONCLUSION The test substance is not harmful to invertebrates

TEST FACILITY US EPA (1987b)

C.2.3. Algal Growth Inhibition Test (Study 1)

TEST SUBSTANCE 14C-labeled urea (surrogate for the notified chemical)

METHOD OECD TG 201 Alga, Growth Inhibition Test
Species *Skeletonema costatum*
Exposure Period 96 hours
Concentration Range Nominal: 6.3-100 mg/L
Auxiliary Solvent dimethylformamide
Analytical Monitoring None
Remarks – Method As per OECD test guidelines. The following deviation was noted: Due to difficulties in detecting the notified chemical in saltwater algal medium, 14C-labeled urea was used as a surrogate for the notified chemical.

RESULTS

Biomass		Growth	
NOEC (mg/L at 96 h)	*EyC50 (mg/L)*	*NOEC (mg/L at 96 h)*	*ErC50 (mg/L)*
25	50	25	99

Remarks – Results The following validity criteria were met. Cell density of the control increased by a factor of 43 after 72 hours and the coefficient of variation for specific growth rates was 4.1%.

	The section-by-section specific growth in control rates in control replicates exceeded the limit of 35% with a value of 62.1%.
CONCLUSION	The test substance is not harmful to algal growth. However, the results from this test should be treated with some caution.
TEST FACILITY	Wildlife International (2016a)

C.2.4. Algal Growth Inhibition Test (Study 2)

TEST SUBSTANCE	Notified chemical (15-25% purity)
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Navicula pelliculosa*
Exposure Period	96 hours
Concentration Range	Nominal: 6.3 - 100 mg/L
Auxiliary Solvent	dimethylformamide
Analytical Monitoring	None
Remarks – Method	As Per OECD test guidelines. No deviations were noted.

RESULTS

Biomass		Growth	
NOEC (mg/L at 96 h)	*ErC50 (mg/L)*	*NOEC (mg/L at 96 h)*	*EyC50 (mg/L)*
50	>100	50	>100

Remarks – Results	The following validity criteria were met. Cell density of the control increased by a factor of 140 after 72 hours and the coefficient of variation was 0.68. The section-by-section specific growth in control rates in control replicates slightly exceeded the limit of 35% with a value of 36.7%. This is not expected to affect the overall outcome of the test.
CONCLUSION	The test substance is not harmful to algal growth.
TEST FACILITY	Wildlife International (2016b)

C.2.5. Algal Growth Inhibition Test (Study 3)

TEST SUBSTANCE	Notified chemical (15-25% purity)
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Pseudokirchneriella subcapitata*
Exposure Period	96 hours
Auxiliary Solvent	dimethylformamide
Analytical Monitoring	None
Remarks – Method	As per OECD test guidelines. No deviations were noted.

RESULTS

Biomass		Growth	
NOEC (mg/L at 96 h)	*ErC50 (mg/L)*	*NOEC (mg/L at 96 h)*	*EyC50 (mg/L)*
50	85	50	65

Remarks – Results	All validity criteria were met. Cell density of the control increased by a factor of 54 after 72 hours and the coefficient of variation for specific growth rates was 4% and 6.3% in section-by-section growth rate.

CONCLUSION	The test substance is harmful to algal growth.
TEST FACILITY	Wildlife International (2016c)

C.2.6. Acute Toxicity to Earthworms

TEST SUBSTANCE	Analogue 1
METHOD	OECD TG 207 Earthworm, Acute Toxicity Test
Species	*Eisenia foetida*
Exposure Period	14 days
Concentration Range	320 – 3200 mg/kg
Remarks – Method	As per OECD test guidelines. No deviations were noted.
RESULTS	No mortalities were observed in any test concentrations.
EC50	> 3,200 mg/kg
Remarks – Results	No mortalities or abnormalities were observed in the control sample.
CONCLUSION	The test substance is not harmful to earthworms.
TEST FACILITY	US EPA (1987c)

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