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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in ANTI-TERRA P

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 on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1712	ResChem Technologies Pty Ltd	Chemical in ANTI-TERRA P	Yes	< 10 tonnes per annum	Component of paints and coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the notified chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the notified chemical is presented in the following table.

Hazard Classification	*Hazard Statement*
Eye damage/eye irritation (Category 2B)	H320 – Causes eye irritation
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

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*
Chronic Category 2	H411-Toxic to aquatic life with long lasting effects

Human Health Risk Assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment
On the basis of the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - Skin sensitisation (Category 1): H317 – May cause an allergic skin reaction
  - Eye damage/eye irritation (Category 2B): H320 – Causes eye irritation

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical during reformulation or use of the finished products:
  - Enclosed/automated processes
  - Local exhaust ventilation
  - Spray booth

- 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 reformulation or during final use:
  - Avoid contact with skin and eyes
  - Avoid inhalation of aerosols or mists

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

- 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 physical containment, 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 paints and coatings, 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.

No additional secondary notification conditions are stipulated.

Safety Data Sheet
The SDS of the 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)
ResChem Technologies Pty Ltd (ABN: 90 315 656 219)
Unit 9, 1 Jubilee Avenue
WARRIEWOOD NSW 2102

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: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for Hydrolysis as a function of pH, Dissociation constant, and Particle size.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU (2018)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
ANTI-TERRA P

MOLECULAR WEIGHT
< 1,000 g/mol

ANALYTICAL DATA
Reference HPLC/UV/MS, ^{1}H NMR/^{13}C NMR, and GC/IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Dark brown solid (as neat substance) or Yellow solution (in organic solvent at ≤ 20% concentration)

Property	*Value*	*Data Source/Justification*
Melting Point	90°C at 98.3 kPa	Measured
Boiling Point	199.45°C at 98.1 kPa	Measured
Relative Density	940 kg/m^3 at 20 °C	Measured
Vapour Pressure	0.085 kPa at 20 °C	Measured
Water Solubility	< 0.03 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities but significant hydrolysis is not expected in the environmental pH range of 4-9
Partition Coefficient (n-octanol/water)	log Pow = 2.76 – 4.38	Measured
Adsorption/Desorption	log Koc = 3.04 – 4.63	Measured

Property	*Value*	*Data Source/Justification*
Dissociation Constant	Not determined	Contains potential cationic functionalities and is likely ionised in the environmental pH range of 4-9
Surface Tension	57.5 mN/m at 20 °C	Measured
Particle Size	Not determined	The notified chemical is only available as a solution.
Flash Point	26 °C	SDS (for the product containing the notified chemical (at < 20%)
Flammability	Not flammable	Measured
Autoignition Temperature	> 100 °C at 98.1 KPa	Measured
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties.

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 be imported into Australia at ≤ 20% concentration for reformulation into coatings and paints.

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
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 25 kg drums and will be transported by road or rail within Australia.

USE
The chemical will be used as a component of coatings and paints at ≤ 1.5% concentration for industrial and professional use. The notified chemical will not be available for the general public use (e.g. DIY).

OPERATION DESCRIPTION
At the reformulation facilities, the imported product containing the notified chemical (at ≤ 20% concentration) will be manually weighed, or metered into mixing vessels. The notified chemical will first be mixed with pigments and resin to form the mill base, which will then be pumped into larger mixing vessels to which further components will be added to form the finished coating products. The finished product (at ≤ 1.5% concentration) will be fed into containers by gravity from the bottom of the mixing vessel through a filter and filling lines. Exhaust ventilation is expected to be used during the whole reformulation process.

Application - End-users
The reformulated product at ≤ 1.5% of the notified chemical will be applied by professional workers via spray (75%), brush (20%) or roller (5%). Spray applications are expected to be conducted in spray booths at industrial sites.

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)*
Stevedore	1	5
Transport	2	5
Storage	5	10
Coating production	6	100
Quality control	2	100
Application	6	100

EXPOSURE DETAILS

Transport and warehouse workers

Transport, storage and stevedore workers are not expected to be exposed to the notified chemical except in the unlikely event of an accident.

Reformulation

Dermal and ocular exposure of the reformulation workers to the notified chemical at ≤ 20% concentration may occur during manual blending process, quality control, equipment cleaning and maintenance. Exposure to the notified chemical is expected to be minimised by the use of local exhaust ventilation and personal protection equipment (PPE) including impervious gloves, goggles, protective clothing and a respirator as stated by the notifier.

Application - End-users

The finished coatings and paints containing the notified chemical at ≤ 1.5% concentration will be used in industrial applications and by professional painters. Applications of coatings or paints to surfaces will be either by spray, brush or roller. Dermal, ocular and inhalation exposure to the notified chemical (at a concentration of ≤ 1.5%) may occur when applying the coatings. Exposure is expected to be minimised by the stated use of PPE (including goggles, impervious gloves, protective clothing) and the use of spray booths during spray application. Inhalation exposure will be further mitigated through the use of exhaust ventilation, and closed processes.

Once the coating is dried, the notified chemical will be bound into an inert solid matrix and will not be available for exposure.

6.1.2. Public Exposure

Products containing the notified chemical will only be for industrial and professional use and will not be sold to the public. The public may come into dermal contact with substrates on which the coatings have been applied. Once the coatings are dried, the notified chemical will be bound into an inert solid matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

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

Endpoint	***Result and Assessment Conclusion***
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw low toxicity
Skin irritation – In vitro EPISKIN model test	non-irritating
Eye irritation – In Vitro Eye Irritation Test in Isolated Chicken Eyes	irritating
Skin sensitisation – mouse local lymph node assay	evidence of sensitisation
Repeat dose oral toxicity – rat, (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental test)	NOAEL > 1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic

Endpoint	*Result and Assessment Conclusion*
Genotoxicity – *In Vitro* Mammalian Cell Gene Mutation Test (HPRT Assay)	non genotoxic
Genotoxicity – *in vitro* - In vitro chromosome aberration	non genotoxic

Toxicokinetics, Metabolism and Distribution
Given the relatively high molecular weights (< 1,000 g/mol) the notified chemical is not expected to be absorbed across the gastrointestinal tract if exposed.

Acute Toxicity
Based on an acute oral toxicity study conducted in rats, the notified chemical is of low toxicity (LD50 > 2,000 mg/kg bw).

Irritation and Sensitisation
According to the results of a skin irritation *in vitro* assay (in vitro EPISKIN model test), the notified chemical was non-irritating. An i*n vitro e*ye irritation test in isolated chicken eyes showed slight corneal swelling and opacity and the notified chemical was considered as an eye irritant.

The notified chemical was shown to be strong skin sensitiser in an LLNA skin sensitisation test with an EC3 of < 0.5%.

Repeated Dose Toxicity
A 28 day repeated dose toxicity study combined with a reproduction/developmental toxicity test by oral gavage to Wistar rats at dose levels of 100, 300 or 1000 mg/kg bw/day was conducted with the notified chemical. The no observed adverse effect level (NOAEL) for the notified chemical was considered to be 1000 mg/kg bw/day for systemic toxicity and for reproductive and developmental toxicity based on an absence of adverse treatment related effects at the highest dose

Mutagenicity/Genotoxicity
The notified chemical was not mutagenic in a bacterial reverse mutation assay, and was not genotoxic in an *in vitro* mammalian chromosome aberration and *in vitro* mammalian cell gene mutation tests.

Health Hazard Classification
Based on the available information, the notified chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the notified chemical is presented in the following table.

Hazard Classification	*Hazard Statement*
Eye damage/eye irritation (Category 2B)	H320 – Causes eye irritation
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the toxicological information provided, the notified chemical is an eye irritant and a skin sensitiser. Therefore, caution should be exercised when handling the notified chemical.

Reformulation
During reformulation, workers may be at risk of skin sensitisation or eye irritation effects when handling the notified chemical at ≤ 20% concentration. This risk should be reduced through the expected use of PPE (coveralls, impervious gloves and safety glasses) and engineering controls (enclosed, automated processes and local exhaust ventilation) which should minimise worker exposure.

Application - End-users
During end use, workers may at risk of sensitisation or eye irritation effects when handling finished coatings containing the notified chemical at ≤ 1.5% concentration. This risk should be reduced through the expected use of PPE (coveralls, impervious gloves and safety glasses), including the use of respiratory protection during spray application, which should minimise exposure. Inhalation exposure should be further mitigated through the use of

exhaust ventilation and spray booths, where possible. After application and once dried, the notified chemical will be cured into an inert solid matrix and will not be available for exposure

Therefore, provided that PPE is worn by workers and engineering controls are in place to limit exposure, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

Paints and coating products containing the notified chemical will be for industrial use only and will not be made available to the public. The public may come into contact with surfaces that have been coated with the notified chemical. However, once the coatings are dried, the notified chemical will be bound into an inert solid matrix and will not be available for exposure.

Therefore, 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 will be imported as a component of formulations for reformulation into paint and coating products. Reformulation will involve transferring the formulations into a mixing vessel, blending with other ingredients, and then filling into end use containers. Empty import containers and reformulation equipment are expected to be cleaned with water and the wastewater is expected to be reused where possible. Accidental spills or leaks of the notified chemical during import, reformulation, storage and transport is expected to be absorbed on suitable materials and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be used as a component of industrial and professional paints and coatings. The paints and coatings will be applied primarily through spraying, but could also involve brush and roller application.

The main release of the notified chemical is likely from overspray during use, estimated by the notifier to account for up to 20% of the total import volume. As the paints and coatings will be applied within designated spray booths, the overspray is expected to be collected in spray booth filters. The spray booth filters and the solvent waste from cleaning of the application equipment are expected to be disposed of in accordance with local government regulations. During use, the notified chemical may also be released to the environment as accidental spills. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified chemical is expected to share the fate of the article to which it has been applied, to be disposed of to landfill or possibly enter metal recycling at the end of their useful lives. Residual notified chemical in empty end-use containers is expected to be cured into an inert solid matrix and be disposed of to landfill along with the empty containers.

7.1.2. Environmental Fate

A biodegradation test conducted on the notified chemical shows that it is not readily biodegradable (14.5 - 48.1 % degraded after 28 days in OECD TG 301B test). For details of the biodegradation test, see Appendix C. As a result of its use pattern, most of the notified chemical is expected to share the fate of the article to which it has been applied, to be disposed of to landfill at the end of their useful lives. A small amount of the notified chemical is also expected to enter landfill as collected wastes and residues. In landfill, the notified chemical will be present as cured solids and will be neither bioavailable nor mobile. The notified chemical is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, nitrogen and phosphorous, or combusted during metal recycling.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified chemical to the aquatic environment will be limited based on its reported use pattern.

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 LL50 > 5 mg/L WAF*	Fish is not the most sensitive test organism to the notified chemical
Daphnia Toxicity	48 h EL50 = 57 mg/L WAF*	Harmful to aquatic invertebrates
Algal Toxicity	72 h EL50 = 4.8 mg/L WAF* 72 h NOEL = 3.2 mg/L WAF*	Toxic to algae
Inhibition of Bacterial Respiration	3 h IC50 > 1,000 mg/L	Not inhibitory to microbial respiration in STPs

**WAF: Water Accommodated Fraction*

Based on the above ecotoxicological endpoints for the notified chemical, it is expected to be toxic to aquatic organisms. Therefore, the notified chemical is formally classified as "Acute Category 2; Toxic to aquatic life" according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Based on the acute toxicity and lack of rapid degradability, the notified chemical is formally classified as "Chronic Category 2; Toxic to aquatic life with long lasting effects" under the GHS (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration (PNEC)

The predicted no-effects concentration (PNEC) has been calculated based on the most sensitive endpoint for fish as shown in the table below. An assessment factor of 100 was used given the acute endpoint for three trophic levels is available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
72 h EL50 for algae	4.8	mg/L
Assessment Factor	100	
Mitigation Factor	1	
PNEC	48	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has not been calculated as release of the notified chemical to the aquatic environment will be limited based on its assessed use pattern. Therefore, based on the assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point 90 °C at 98.3 kPa

Method	OECD TG 102 Melting Point/Melting Range EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks	A capillary tube in a metal block method.
Test Facility	CiToxLAB (2016a)

Boiling Point 199.45 °C at 98.1 kPa

Method	OECD TG 103 Boiling Point EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Capillary method
Test Facility	CiToxLAB (2016b)

Relative Density 940 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids EC Council Regulation No 440/2008 A.3 Relative Density
Remarks	Pycnometer method
Test Facility	Chilworth (2016a)

Vapour Pressure 0.085 kPa at 20 °C

Method	OECD TG 104 Vapour Pressure EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	Vapour Pressure Balance method
Test Facility	Chilworth (2016b)

Water Solubility < 0.03 g/L at 20 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Column Elution Method; the solubility of the test substance is lower than the limit of quantitation.
Test Facility	FumoPrep (2017)

Partition Coefficient (n-octanol/water) log Pow = 2.76 – 4.38

Method	OECD TG 117 Partition Coefficient (n-octanol/water) EC Council Regulation No 440/2008 A.8 Partition Coefficient
Remarks	HPLC Method; the column temperature is 25°C; the test substance is surface active
Test Facility	CiToxLAB (2016j)

Adsorption/Desorption log K_{oc} = 3.04 – 4.63

Method	OECD TG 121 Adsorption Coefficient EC Council Regulation No 440/2008 C.19 Adsorption Coefficient
Remarks	HPLC Method; the column temperature is 25°C
Test Facility	CiToxLAB (2016k)

Surface Tension 57.5 mN/m at 20 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions EC Council Regulation No 440/2008 A.5 Surface Tension
Remarks	Test concentration: 90% of the saturation solubility; the test substance is surface active
Test Facility	CiToxLAB (2017)

Flammability Not flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids)
Remarks	The flame from a gas burner was applied to the test item for 2 minutes and the test item did not ignite. The test was carried out in duplicate.The item is considered not to be highly flammable.
Test Facility	CiToxLAB (2016c)

Autoignition Temperature > 100 °C at 98.1 KPa

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids
Remarks	The test item was only heated to 100 °C as the melting temperature is 90 °C. Three experiments were done to the test item. A steady rise in temperature of the oven (by 0.5 °C/min rate) and the sample was observed with no indication of auto ignition of the test item.
Test Facility	CiToxLAB (2016d)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method (2001) EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/ Crl:WI
Vehicle	Propylene glycol / 1% Tween 80 (Polysorbate 80)
Remarks – Method	There were deviations from the study plan, but they are not expected to significantly affect the result (Temperature 18.6 °C instead of 22±3 °C and humidity 80% instead of 30-70%) during the study. GLP compliant.

RESULTS

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

LD50	> 2,000 mg/kg bw
Signs of Toxicity	Hunched back and incoordination was observed in all animals, with symptoms clearing by the 24 hour observation.
Effects in Organs	No macroscopic abnormalities were found.
Remarks – Results	No mortalities occurred. Body weight gains of the animals showed no test item related effects.
CONCLUSION	The notified chemical is of low acute toxicity via the oral route.
TEST FACILITY	CiToxLAB (2016e)

B.2. Skin Irritation – *In Vitro* Skin Irritation Test in the EPISKINTM (SM)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method (2015)
Vehicle	Phosphate Buffered Saline (PBS)
Remarks – Method	GLP Compliant No significant protocol deviations. Negative control: PBS Positive control used: 5% (w/v) Sodium Dodecyl Sulphate (SDS)

RESULTS

Test Material	*Mean OD_{570} of Triplicate Tissues*	*Relative Mean Viability (%)*	*SD of Relative Mean Viability*
Negative control	0.650	100.0	0.048
Test substance	0.609	91.7*	5.1
Positive control	0.033	5.1	0.3

OD = optical density; SD = standard deviation

* Calculated using the optical density value after it was corrected for non-specific MTT reduction, which gave a value of 0.596.

Remarks – Results	The mean cell viability of the test item compared to the negative control was 91.7%. The test item was considered as non irritant as the mean cell viability was above the threshold of 50%.

CONCLUSION	The notified chemical was considered non-irritating to the skin under the conditions of the test.
TEST FACILITY	CiToxLAB (2016f)

B.3. Eye Irritation – *In Vitro* Eye Irritation Test in Isolated Chicken Eyes

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 438 Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants (2013)
Vehicle	None
Remarks – Method	The test substance was directly administered to the isolated chicken eyes. The control eyes and test eyes were evaluated at approximately 30, 75, 120, 180 and 240 minutes after the post-treatment rinse. Corneal thickness and corneal opacity were measured at all time points. Fluorescein retention was measured on two occasions, at base line (t = 0) and approximately 30 minutes after the post-treatment rinse Negative Control: Physiological saline solution (0.9% (w/v) NaCl) Positive Control: Imidazole

RESULTS

Test Material	*Mean Maximum Corneal Swelling (%)*		*Mean Maximum Corneal Opacity*	*Mean Fluorescein Retention*
	75 min	*240 min*		
Vehicle control	0.0	0.0	0	0
Test substance	1.1	2.2	0.67	0.83
Positive control	14.3	30.8	4.00	3.00

Remarks – Results	Slight corneal swelling and corneal opacity along with very slight fluorescein retention were observed in all three eyes treated with the test substance. Particles of the test substance were stuck on the cornea surface and not cleared after the post treatment rinse. A microscopic evaluation of two sections of each treated cornea showed a very slight erosion of the corneal epithelium in most sections (5/6 sections) with no stromal or endothelial changes. Negative control and positive control results were in good correlation with the historical control data and confirmed the validity of the test. Based on the histopathological data, the notified chemical was considered an eye irritant.
CONCLUSION	The notified chemical was considered an eye irritant under the conditions of the test.
TEST FACILITY	CiToxLAB (2016g)

B.4. Skin Sensitisation – LLNA

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429 Skin Sensitisation: Local Lymph Node Assay (2010) EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain	Mouse/CBA/CaOlaHsd
Vehicle	Methyl ethyl ketone (MEK).

Preliminary study	Yes. The preliminary test was performed using 50 & 25% in AOO and 10, 5, 2.5 & 1% in methyl ethyl ketone (MEK). 5 % dose was selected for the main test top dose due to local irritation or systemic toxicity.
Positive control	The positive control α-Hexylcinnamaldehyde (HCA) (dissolved in MEK) was conducted in parallel with the test substance.
Remarks – Method	No major deviations from the test guideline were reported.

RESULTS

Concentration (% w/w)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node)*	*Stimulation Index (test/control ratio)*
Test Substance			
0 (vehicle control)	4F	516.2	1.0
0.5	4F	2494.9	4.8
1	4F	2265.7	4.4
2.5	4F	1831.7	3.5
5	4F	1987.7	3.9
Positive Control			
25% w/v HCA in MEK	4F	4517.8	8.8

EC3	< 0.5%
Remarks – Results	No mortalities, systemic toxicity, or irritancy was noted during the study. No marked body weight losses (≥ 5%) were noted on the mean body weight change except for one animal in the 5, 1 and 0.5% dose groups and a body weight increase (at ≥ 5%) for one animal in the negative control group, 2.5, 1, and 0,5% dose groups and the positive control group. A lymphoproliferative response in line with historic positive control data was noted for the positive control chemical, confirming the validity of the assay.

CONCLUSION There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY CiToxLAB (2016h)

B.5. Repeat Dose Oral Toxicity in Rats Combined with the Reproduction/Developmental Toxicity Screening Test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test

Species/Strain	Rats/ Crl:WI
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week 14 days pre-mating, Mating up to 5 days, Gestation 21-24 days, and 13 days lactation period.
Vehicle	Propylene glycol containing 1% (v/v) Tween 80
Remarks – Method	No significant protocol deviations. GLP compliant. Based on the results from the preliminary studies, the Dose Range Finding was 1000 mg/kg bw/day where no toxicity was observed and doses of 100, 300 and 1000 mg/kg bw/day were selected for the main study.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
Control	12M, 12F	0	0/24
Low Dose	12M, 12F	100	1/24
Mid Dose	12M, 12F	300	0/24
High Dose	12M, 12F	1000	0/24

Mortality and Time to Death

All animals survived to the scheduled necropsy except one female animal in the low dose group was found dead on Day 27. The cause of death was acknowledged by the study author as a gavage accident.

Clinical Observations

No treatment-related clinical signs were observed except one high dose female animal showed crouching and hunched back on Day 6 to 9 and hunched back, red liquid at the vulva, piloerection and red discharge at the nose on Day 30 to 32. No statistically significant changes in body weight or body weight gain were recorded in the treated groups. No test item related differences in the mean daily food consumption were noted in any treated groups compared to the controls. No adverse effects in neurological behaviour were observed in animals exposed to the test item.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were no treatment related adverse effects in the measured haematological parameters. However, significantly lower ($p < 0.05$) prothrombin time (PTT) was measured in males dosed with 100 mg/kg bw/day of the test item, however the values were within the historical control range.

Urine volumes showed a statistically significant increase in male animals in the 100 mg/kg bw/day dose group and female animals in the 1000 mg/kg bw/day dose group, the values were well within the historical control range.

Effects in Organs

No treatment-related macroscopic findings were noted in any of the dose groups at necropsy and no treatment related microscopic effects were observed at histopathology. There were no treatment-related differences between groups in the weights of organs compared to control groups.

Reproductive and developmental findings

No treatment related effects on fertility and reproductive performance were observed. No effect was observed on the mean number of *corpora lutea,* and implantation sites. No treatment-related effects were observed during the pre-implantation and gestation periods. No treatment-related effects on the mean number of pups delivered, mean pup weights and the sex ratio were observed.

Offspring (F1) Generation

There were no treatment-related effects on pup mortality and on the viability of pups on PND0, 4 and 13. However the animals of the high dose group were comparable to the controls, except one female had 14 pre-natal losses (out of 16 implantation sites) and the two remaining liveborns died before PND4. This pre-natal mortality incidence was considered by the study author as not treatment-related as this was due to a single litter, not statistically significant, and within the normal range.

There were no toxicologically significant differences differences in the offspring body weights or weight gains when compared to controls.

There were no treatment-related effects on the thyroid hormone levels or on the thyroid gland weights in the PND13 pups. However, a significantly higher ($p < 0.01$) T4 concentration was noted in the high dose PND13 pups, but the value noted remained within the historical control range.

Overall, no treatment-related microscopic or macroscopic findings were seen at dose levels up to 1000 mg/kg bw/day at necropsy.

Remarks – Results

There were no adverse treatment related effects observed in any of the systemic, reproductive or developmental parameters measured.

CONCLUSION
The NOAEL for toxicity in the parental animals was established as > 1000 mg/kg bw/day based on an absence of adverse treatment related effects at the highest dose.

The NOAEL for reproductive and developmental toxicity was established as 1000 mg/kg bw/day in both male and female animals based on an absence of adverse treatment related effects at the highest dose.

TEST FACILITY CiToxLAB (2018a)

B.6. Genotoxicity – Bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test (1997)
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria
Plate incorporation procedure

Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98 and TA100 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 10, 31.6, 100, 316, 1,000, 2,500 and 5,000 µg/plate b) Without metabolic activation: 0.5 – 5,000 µg/plate
Vehicle	n-Hexane
Remarks – Method	No significant protocol deviations

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 2500	≥ 5000	≥ 158.1	negative
Test 2		> 5000	≥ 158.1	negative
Present				
Test 1	> 5000	> 5000	≥ 158.1	negative
Test 2		≥ 5000	≥ 158.1	negative

Remarks – Results
No relevant increase in the number of revertant colonies of any of the tested strains were observed following treatment with the test substance at any dose level, either with or without metabolic activation.

The mean values of the revertant colonies of the solvent control correlated with the historical data. The positive controls produced satisfactory responses, confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

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

TEST FACILITY CiToxLAB (2016i)

B.7. Genotoxicity – *In Vitro* Mammalian Chromosome Aberration Test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test (2016)

Species/Strain	Chinese hamster
Cell Type/Cell Line	Lung cells / V79
Metabolic Activation System	S9 mix from β-naphthoflavone/phenobarbitone induced rat liver
Vehicle	Propylene glycol (propane-1,2-diol) and 1% Tween 80 (Polysorbate 80)

Remarks – Method
No significant protocol deviations.
Negative control: Propylene glycol and 1% Tween 80
Positive control:
Ethyl methanesulfonate (EMS) (Without metabolic activation)
Cyclophosphamide monohydrate (CP) (With metabolic activation)

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	150, 125, 100, 75*, 50*, 25* and 12.5*	3 hours	20 hours
Test 2	100, 80, 60*, 40*, 20*, 10*, 5*, 2.5 and 1.25	20 hours	28 hours
Present			
Test 1	200, 150, 125, 100*, 50* and 25*	3 hours	20 hours
Test 2	200, 150, 125, 100*, 75*, 50*, 25, 12.5 and 6.25	3 hours	28 hours

*Cultures selected for metaphase analysis

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 125	≥ 75	≥ 500	negative
Test 2	≥ 125	≥ 60	≥ 125	negative
Present				
Test 1	≥ 250	≥ 100	≥ 500	negative
Test 2	≥ 125	≥ 100	≥ 500	negative

Remarks – Results
There were no statistically significant increase in the number of cells with structural chromosome abberations at any treated concentration, with or without metabolic activation compared to the negative control.

The negative and positive controls produced satisfactory responses, confirming the activity of the S9-mix and the sensitivity of the test.

CONCLUSION
The notified chemical was not clastogenic to Chinese hamster V79 lung cells treated *in vitro* under the conditions of the test.

TEST FACILITY
CiToxLAB (2018c)

B.1. Genotoxicity – *In Vitro* Mammalian Cell Gene Mutation Test

TEST SUBSTANCE
Notified chemical

METHOD
OECD TG 476 *In vitro* Mammalian Cell Gene Mutation Test (2016)
Species/Strain
Chinese hamster
Cell Type/Cell Line
CHO Sub-line (K1)
Metabolic Activation System
S9 mix from β-naphthoflavone/phenobarbitone induced rat liver
Vehicle
Propylene glycol/1% Tween 80
Dimethyl sulfoxide was used as vehicle (solvent) of the positive control
Remarks – Method
No significant protocol deviations
Positive controls used:
In the absence of metabolic activation: Ethyl methanesulfonate (EMS)
In the presence of metabolic activation: 7,12-Dimethylbenz[a]anthracene (DMBA)

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	200, 100, 75, 50, 25, 12.5 and 6.25	5 hours	7 days	7 days
Test 2	70, 60, 50, 40, 30, 20, 10 and 5	24 hours	7 days	7 days
Present				

Test 1	1000, 500, 375, 250, 125, 62.5, 31.25 and 15.625	5 hours	7 days	7 days
Test 2	1000, 500, 375, 250, 125, 62.5, 31.25 and 15.625	5 hours	7 days	7 days

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 62.5	≥ 50	≥ 200	negative
Test 2	≥ 62.5	≥ 40	≥ 60	negative
Present				
Test 1	≥ 250	≥ 250	≥ 250	negative
Test 2		≥ 125	≥ 250	negative

Remarks – Results

The test substance induced cytotoxicity in the absence and presence of S9 metabolic activation.

The test substance did not induce statistically significant increases in the mutant frequency in the presence of S9 metabolic activation or in the absence of metabolic activation when the exposure period was 5 hours, in independent repeated experiments.

In test two in the absence of metabolic activation there was a statistically significant increase in the mutant frequency at doses of 30 and 50 µg/mL ($p < 0.05$). The mutant frequency at 30 and 50 µg/mL was 10.5, which was similar to the untreated control (10.1) with the negative control being 7.7. The mutant frequency at 30 and 50 µg/mL was well within the historical control range for the laboratory and subsequently is not considered to be a positive result.

The mutation frequency of the negative (vehicle) control was consistent with the historical control range in all tests.

The positive and vehicle controls gave satisfactory responses, confirming the validity of the test system.

CONCLUSION

The notified chemical was not clastogenic to CHO K1 Chinese hamster ovary cells treated *in vitro* under the conditions of the test.

TEST FACILITY

CiToxLAB (2018b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge from a domestic sewage treatment plant
Exposure Period	First test: 35 days; Second test: 28 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 by TOC analyser
Remarks – Method	No major deviations from the test guidelines were reported. The test substance was added together with a small amount of glass beads into a vessel. The vessel was shaken for 30 minutes. Then a small amount of mineral medium was added and further shaken for 30 minutes. The dispersions were filled up with more mineral medium to achieve the test concentration. A toxicity control was run.

RESULTS

Day	*Test Substance* *First test % Degradation (range)*	*Second test %Degradation (range)*	*Day*	*Sodium benzoate* *First test % Degradation (mean)*	*Second test %Degradation (mean)*
7	2.3-5.8	3.1-18	7	78.4	73.9
14	8.9-14.1	9.0-29.5	14	88.7	78.9
21	12.2-20.7	14.1-40.6	21	86.9	83.5
28	14.5-27.1	18.5-48.1	28	80.8	86.6
35	15.7-35.1		35	83.3	

Remarks – Results	All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. Two independent tests were performed since in the first test the biodegradation values for the two test item replicates deviated more than 20% from each other. The second test included three replicates. Two of the replicates showed comparable biodegradation values while the third replicate showed higher degradation and deviated from the other two by more than 20%. The test substance is an UVCB. The differences in the biodegradation patterns of the replicates reflect the unequal adaptation of the inocula with slightly different microorganism community composition to a test substance with a complex composition.
CONCLUSION	The test substance is not readily biodegradable.
TEST FACILITY	IES (2018)

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 EC Council Regulation No 440/2008 C.1 Acute Toxicity for Fish – Semi-static
Species	Zebra fish (*Danio rerio*)
Exposure Period	96 hours

Auxiliary Solvent	None
Water Hardness	125 mg $CaCO_3$/L
Analytical Monitoring	High performance liquid chromatography with UV detection (HPLC/UV)
Remarks – Method	No major deviations from the test guidelines were reported. A limit test was conducted based on acute daphnia study result to demonstrate that fish is not the most sensitive test organism to the test substance. A test loading rate of 5 mg/l was prepared and stirred for 48 hours. The dispersion was then filtered, and the water accommodated fraction (WAF) was used for testing. The test water was renewed daily. The test water was sampled at the start and end of each renewal periods for analysis of the test substance.

RESULTS

Concentration (mg/L WAF)		*Number of Fish*	*Mortality*
Nominal	*Measured*		*96 h*
Control	<LOQ*	7	0
5	<LOQ*	7	0

*LOQ: limit of quatification of 1 mg/L

LL50	>5 mg/L at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. Dissolved Oxygen concentration was ≥ 7.5 mg/L at 21°C (≥ 83%; USGS, 2011) during the test.

CONCLUSION Fish is not the most sensitive test organism to the test substance.

TEST FACILITY IES (2017a)

C.2.2. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi-static
EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia – Semi-static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC/UV
Remarks – Method	No major deviations from the test guidelines were reported. However, the nominal concentrations form a geometric progression with a factor exceeding the recommended value of 2.2. Each test loading rate was prepared and stirred for 48 hours. The dispersion was then filtered, and the water accommodated fraction (WAF) was used for testing. The test water was renewed daily. The test water of the control and 32 mg/L and 100 mg/L loading rates was sampled at the start and end of each renewal periods for analysis of the test substance.

RESULTS

Concentration (mg/L WAF)		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	<LOQ*	20	0	0
1.0	Not determined	20	0	0
3.2	Not determined	20	0	0
10	Not determined	20	0	0
32	<LOQ*	20	0	0

100	<LOQ*	20	6	20

*LOQ: limit of quantification of 1 mg/L

EL50	57 mg/L nominal concentration at 48 hours (95%CI of 32-100 mg/L), calculated using the geometric mean.
Remarks – Results	All validity criteria for the test were satisfied. Dissolved Oxygen concentration was ≥ 8.0 mg/L during the test.
CONCLUSION	The test substance is harmful to aquatic invertebrates.
TEST FACILITY	IES (2017b)

C.2.3. Algal Growth Inhibition Test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test EC Council Regulation No 2016/266 C.3 Algal Inhibition Test
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 1, 3.2, 10, 32, 100 mg/L WAF Measured for 1, 3.2 and 10 mg/L loading rates: <LOQ of 1 mg/L
Auxiliary Solvent	None
Water Hardness	15 mg $CaCO_3$/L
Analytical Monitoring	HPLC/UV
Remarks – Method	No major deviations from the test guidelines were reported. Each test loading rate was prepared and stirred for 48 hours. The dispersion was then filtered, and the water accommodated fraction (WAF) was used for testing. The test water of the control and 1 mg/L, 3.2 mg/L and 10 mg/L loading rates was sampled at the start and end of the test for analysis of the test substance. A reference test with potassium dichromate was run as part of a biannual quality assurance program.

RESULTS

Biomass		*Growth*	
EyL50 (mg/L at 72 h)	*NOEL (mg/L)*	*ErL50 (mg/L at 72 h)*	*NOEL (mg/L)*
4.1 (95% CI of 3.5-4.8)	3.2	4.8 (95% CI of 4.5-5.1)	3.2

Remarks – Results	All validity criteria for the test were satisfied, the biomass factor increased by 140 times. The mean coefficient of variation for section-by-section growth rates was 14 %. The coefficient of variation of average specific growth rates during the whole test period in replicate control cultures was 0.9 %. The 72 h ErC50 for algae exposed to potassium dichromate was 1 mg/L which was within the range of expected responses.
CONCLUSION	The test substance is toxic to algae.
TEST FACILITY	IES (2017c)

C.2.4. Inhibition of Microbial Activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test EC Council Regulation No 2016/266 C.3 C.11 Activated Sludge Respiration Inhibition Test
Inoculum	Activated sludge
Exposure Period	3 hours

Nominal Concentration	1,000 mg/L
Remarks – Method	A limited test was conducted based on a range finding test result. No major deviations from the test guidelines were reported.

RESULTS

IC50	> 1,000 mg/L
Remarks – Results	All validity criteria for the test were satisfied.

CONCLUSION	The test substance does not inhibit microbial respiration in STPs.
TEST FACILITY	IES (2016)

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