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AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Octadecene, reaction products with hexadecene, hydrogenated

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. 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 AICIS website. For enquiries please contact AICIS at:

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Executive Director
AICIS

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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/1733	ReOil Pty Ltd	Octadecene, reaction products with hexadecene, hydrogenated	Yes*	≤ 10,000 tonnes per annum	Component of lubricants

*Only if kinetic viscosity is < 20.5 mm^2/s at 40 °C.

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, classification for aspiration hazard is applicable depending on the kinetic viscosity of the assessed chemical, according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. If the kinetic viscosity of the assessed chemical is < 20.5 mm^2/s at 40 °C, the following classification is applicable:

Hazard Classification	*Hazard Statement*
Aspiration hazard (Category 1)	H304 – May be fatal if swallowed and enters airways

Human Health Risk Assessment
Under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

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

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

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- If the kinetic viscosity of the assessed chemical is < 20.5 mm^2/s at 40 °C, the following classification is applicable:
  - Aspiration hazard (Category 1): H304 - May be fatal if swallowed and enters airways

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

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the assessed chemical during reformulation:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation if aerosols or mists are generated

- 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 assessed chemical as introduced or during reformulation and use:
  - Avoid inhalation
  - Avoid ingestion/aspiration

- 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 assessed chemical as introduced or during reformulation:
  - Respiratory protection if inhalation exposure may occur

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

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

- If products and mixtures containing the assessed 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.

Public Health

- As liquid hydrocarbons are included in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), any labelling and/or packaging requirement for products containing the assessed chemical, which are available to the public, should be adhered to.

Storage

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

Emergency procedures

- Spills or accidental release of the assessed chemical should be handled by containment and subsequent safe disposal.

Disposal

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

Regulatory Obligations

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under section 101 of the IC Act the introducer of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the chemical is proposed to be used in spray products;
- the function or use of the chemical has changed from a component of lubricants, 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 human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet
The SDSs of the assessed chemical provided by the applicant were reviewed by AICIS. The accuracy of the information on the SDSs remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT
ReOil Pty Ltd (ABN: 43 610 978 179)
4/1 Shipley Drive
RUTHERFORD NSW 2320

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

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
No details are taken to be protected information.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for hydrolysis as a function of pH, adsorption/desorption, dissociation constant, flammability, explosive properties, oxidising properties and acute inhalation toxicity.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
USA (2019/2020)
EU (2020)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SynNova Base Oil
SynNova 4 Base Oil
SynNova 9 Base Oil

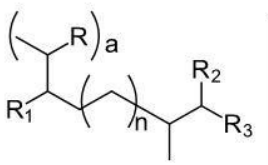
CAS NUMBER
2241366-04-9

CHEMICAL NAME
Octadecene, reaction products with hexadecene, hydrogenated

OTHER NAME(S)
Oligomerisation products of alpha-alkenes C16-18 (even numbered), hydrogenated, hydroisomerised
Methylated distillation products of C16 and 18 linear and branched alpha olefins, hydrogenated
TS20819 (code in study reports)

MOLECULAR FORMULA
Unspecified (UVCB)

STRUCTURAL FORMULA



n = 1 (donates C16 olefin) or 3 (denotes C18 olefin)
R or a = iso-C16-C18 (Me, Et) or H
R1 = iso-C9-C13 (Me)
R2 = C_4H_{10} linear or branched isomers
R3 = iso-C9-C13 (Me) or H
Representative structure of the assessed chemical

MOLECULAR WEIGHT
Typically 224-1010 g/mol (UVCB)

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

3. COMPOSITION

DEGREE OF PURITY
100% (UVCB)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear viscous liquid

Property	*Value*	*Data Source/Justification*
Melting Point/Freezing Point	-39°C at 101.3 kPa (SynNova Base Oil)	Measured*
	-45 °C at 101.3 kPa (SynNova 4 Base Oil)	Measured*
	-39°C at 101.3 kPa (SynNova 9 Base Oil)	SDS
Boiling Point	419 °C at 101.3 kPa (SynNova Base Oil)	Measured*
	400-500 °C at 101.3 kPa (SynNova 4 Base Oil)	SDS
	400-650 °C at 101.3 kPa (SynNova 9 Base Oil)	SDS
Density	823 kg/cm³ at 15 °C (SynNova Base Oil)	Measured*
	819 kg/cm³ at 15 °C (SynNova 4 Base Oil)	Measured*
	840 kg/cm³ at 15 °C (SynNova 9 Base Oil)	SDS
Kinetic Viscosity	25.03 mm²/s at 40°C (Synova Base Oil)	Measured*
	19.38 mm²/s at 40°C (Synova 4 Base Oil)	Measured*
	48 mm²/s at 40°C (Synova 9 Base Oil)	SDS
Vapour Pressure	5.49×10^{-10} kPa at 20 °C (SynNova Base Oil)	Measured
	5.49×10^{-10} kPa at 20 °C (SynNova 4 Base Oil)	SDS
	5.49×10^{-10} kPa at 20 °C (SynNova 9 Base Oil)	SDS
Water Solubility	< 0.21 mg/L at 20 °C (SynNova Base Oil)	Measured
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionalities
Partition Coefficient (n-octanol/water)	log Pow > 4.7 at 20 °C (SynNova Base Oil)	Measured
	log Pow = 15.76 - 31.33	Calculated using EPISUTE
Adsorption/Desorption	log Koc = 8.7 - 17	Calculated using EPISUTE
Dissociation Constant	Not determined	Contains no dissociable functional groups

Property	*Value*	*Data Source/Justification*
Flash Point	235 °C at 101.3 kPa C (SynNova Base Oil)	Measured
	235 °C at 101.3 kPa C (SynNova 4 Base Oil)	SDS
	235 °C at 101.3 kPa C (SynNova 9 Base Oil)	SDS
Flammability	Not determined	Not expected to be highly flammable based on the measured flash point
Autoignition Temperature	350 °C (SynNova Base Oil)	Measured
	305 °C (SynNova 4 Base Oil)	SDS
	305 °C (SynNova 9 Base Oil)	SDS
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidising properties

* Study reports were not provided.

DISCUSSION OF PROPERTIES

The three marketed products (SynNova Base Oil, SynNova 4 Base Oil and SynNova 9 Base Oil) are different in composition in terms of monomers, dimers, trimers and higher tier components. The measured kinetic viscosity provided for SynNova 4 Base Oil is 19.38 mm^2/s at 40 °C. According to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, hydrocarbon substances with viscosity < 20.5 mm^2/s at 40 °C should be classified for aspiration hazard. See Section 6.2 for further details regarding the health hazard classification.

For details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

The assessed 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 assessed 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.

The assessed chemical has a flash point of 235 ºC which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the assessed chemical may be considered as a Class C2 combustible liquid if the chemical has a fire point below the boiling point.

5. INTRODUCTION AND USE INFORMATION

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

The assessed chemical will not be manufactured in Australia. It will be imported into Australia in the neat form for reformulation into finished products. It may also be imported in finished products at 10-99.5% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	200	1000	5000	10000	10000

PORT OF ENTRY

Port Jackson and Sydney

IDENTITY OF RECIPIENT

ReOil Pty Ltd

TRANSPORTATION AND PACKAGING

The assessed chemical will be imported in the neat form in IBCs or ISO tanks and transported by road within Australia. It may also be imported in finished lubricants. The finished lubricants containing the assessed chemical at 10-99.5% concentration will be distributed nationwide by road and rail.

USE

The assessed chemical will be used as a component of lubricants (at 10-99.5% concentration) which will be primarily used by industrial and professional users in industry where lubricants are typically utilised. Finished lubricants (containing 10-99.5% assessed chemical) in small containers will be available for do-it-yourself (DIY) users to replace or top-up automotive lubricants.

OPERATION DESCRIPTION

Reformulation

The imported assessed chemical (at 100% concentration) will be formulated into end-use lubricants. The reformulation procedure will likely vary depending on the nature of the formulated products, and may involve both automated and manual transfer steps. However, in general, it is expected that the reformulation processes will involve blending operations that will be highly automated and use closed systems with adequate ventilation, followed by automated filling of the reformulated products into containers of various sizes (50, 100 and 200 L drums for industrial use and 1, 5 and 10 L containers for DIY use). Quality control analysis, cleaning and maintenance of the blending vessels and filling lines will also occur.

End-use

The finished lubricants containing the assessed chemical at 10-99.5% concentration will be added to equipment manually or through automated, closed systems.

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	12
Operators	Up to 4	100
QC samplers	1	100
Cleaning and maintenance	Up to 8	52
Industrial/Professional end-users	Up to 1	200

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the assessed chemical only in the event of accidental rupture of packages.

Reformulation

During reformulation, dermal, ocular and inhalation (if oil mists are generated) exposure of workers to the assessed chemical at up to 100% concentration may occur during the blending and filling operations, quality control analysis, packaging of materials and cleaning and maintenance of equipment. Exposure should be mitigated by the use of enclosed, automated systems and personal protective equipment (PPE: goggles, impervious gloves, protective clothing and respiratory protection if inhalation exposure may occur), as anticipated by the applicant.

End-use

Dermal, ocular and inhalation (if oil mists are generated) exposure to the assessed chemical at ≤ 99.5% concentration may occur during transfer of the finished lubricant products from the storage containers into the machinery reservoirs, and during cleaning and maintenance of equipment. Exposure should be limited by the use of ventilated environments and PPE (goggles, impervious gloves, protective clothing and respiratory protection if inhalation exposure may occur), as anticipated by the applicant.

6.1.2. Public Exposure

Finished lubricants (containing 10-99.5% assessed chemical) in small containers may be used by DIY users to replace or top-up automotive lubricants. In these cases, dermal and ocular exposure may occur; however, such exposure is expected to be of a short duration and on an infrequent basis.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the assessed 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
Acute dermal toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation – *in vitro* EpiSkin reconstituted human epidermis test	non-corrosive or irritating
Eye irritation – *in vitro* Isolated chicken eye test	no classification for eye irritation or serious eye damage
Skin sensitisation – mouse local lymph node assay	no evidence of sensitisation
Combined repeat dose oral toxicity with reproductive/developmental toxicity screening test – rat, 29 days (males), ~68 days (females)	NOAEL > 1,000 mg/kg bw for systemic, reproductive and developmental toxicity; non genotoxic
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vivo* mammalian chromosome aberration	non genotoxic
Genotoxicity – *in vitro* mammalian cell gene mutation test	non genotoxic

Toxicokinetics

Given the assessed chemical has components of low molecular weight (< 500 g/mol), absorption across biological membranes may occur, but would be limited by the low water solubility (< 0.21×10^{-3} g/L at 20 °C) and high partition coefficient (log Pow > 4.7 at 20 °C). The assessed chemical may also be taken up by micellular solubilisation due to its high lipophilicity.

Acute Toxicity

Based on acute oral and dermal toxicity studies conducted in rats, the assessed chemical is reported to be of low oral and dermal toxicity (LD50 > 2000 mg/kg bw/day).

Irritation and Sensitisation

According to the results of a combined *in vitro* skin corrosion and irritation study using EpiSkin™ reconstructed human epidermis test model, the assessed chemical is considered to be non-corrosive and not classified as a skin irritant.

The assessed chemical does not require classification for eye irritation or serious eye damage, based on the results in an *in vitro* isolated chicken eye (ICE) test.

Sensitisation

The assessed chemical was not a skin sensitiser in an *in vivo* mouse local lymph node assay.

Repeated Dose Toxicity

In a combined repeated dose oral toxicity study with reproduction/developmental screening test, the assessed chemical was administered (oral gavage) in rats at doses of 100, 300 and 1,000 mg/kg bw/day for up to 29 days for males and ~68 days for females. The No Observed Adverse Effect Level (NOAEL) for systemic, reproductive and developmental toxicity was established as > 1,000 mg/kg bw/day, based on no test substance-related effects were observed up to the highest dose level.

Adverse effects after repeated inhalation exposure were reported for an analogue chemical, 1-tetradecene, homopolymer, hydrogenated (CAS No. 1857296-89-9) (NICNAS, 2020). The analogue chemical was tested in a 28-day repeated dose inhalation study in rats with doses up to 2.35 mg/L with a 2-week recovery period. Dose related effects in organ weight and microscopic changes were seen in the respiratory system, particularly the lungs and bronchi, and did not resolve after the recovery period. Blood cell counts were also affected. The effects were interpreted as an inflammatory response to irritation, and accumulation of the test substance in the lungs, with associated effects in the local and draining lymph glands. A NOAEC of 0.75 mg/L was set based on the severity of the effects at the highest dose.

Mutagenicity/Genotoxicity
The assessed chemical was negative in a bacterial reverse mutation assay, an *in vitro* mammalian chromosome aberration test using Chinese hamster V79 cells, and an *in vitro* mammalian cell gene mutation test using mouse lymphoma L5178Y cells. In a micronucleus test integrated into the combined repeat dose oral toxicity with reproductive/developmental toxicity screening test in rats (described above), no increase in bone marrow cells with micronuclei was observed after the repeated treatments; however, there was no reported evidence of the chemical reaching bone marrow of the tested animals.

Health Hazard Classification
Based on the available information, classification for aspiration hazard is applicable depending on the kinetic viscosity of the assessed chemical, according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. If the kinetic viscosity of the assessed chemical is < 20.5 mm^2/s at 40 °C, the following classification is applicable:

Hazard Classification	***Hazard Statement***
Aspiration hazard (Category 1)	H 304 – May be fatal if swallowed and enters airways

6.3. Human Health Risk Characterisation
Classification for aspiration hazard is applicable depending on the kinetic viscosity of the assessed chemical. No inhalation toxicity data were available for the assessed chemical, but an analogue chemical indicated adverse effects following repeated inhalation exposure.

6.3.1. Occupational Health and Safety
Workers handling lubricants containing the assessed chemical may come into contact with the chemical at up to 100% concentration during reformulation or equipment servicing. Ingestion/aspiration is unlikely to occur in the proposed use of the chemical, except in case of an accident. The risk would be reduced by the controlled environment in which some of the processes occur by safe work practices, and further reduced by the stated use of PPE by workers. Given the low vapour pressure of the assessed chemical and the use of enclosed automated systems with adequate ventilation during the reformulation process, inhalation exposure and risk is likely to be low.

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

6.3.2. Public Health
The risk to DIY users from manual addition of products containing the assessed chemical (up to 99.5%) to automobiles is not considered unreasonable as only incidental exposure is expected and the frequency of use is expected to be low. Furthermore, labelling of products is expected to contain adequate information to warn users regarding any hazards of the lubricant and safety directions for use.

The assessed chemical is a liquid hydrocarbon. Liquid hydrocarbons are included in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) (SUSMP, 2020), with packaging/labelling requirements for products containing liquid hydrocarbons available to the public.

When used in the proposed manner, the assessed 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 assessed chemical will be imported as a component of finished lubricant or in neat form for reformulation into the finished products. In general, the reformulation process is expected to involve blending operations that will be highly automated in closed systems, followed by automated filling of the reformulated products into containers. Waste generated from the reformulation process and accidental spills containing the assessed chemical are

expected to be collected and then either re-used to a practicable extent or disposed of to landfill, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

A majority of the assessed chemical will be used for various industrial purposes including, but not limited to metal working fluids, release agents, rubber production and binding, polymer processing and functional fluids. Wastes of the assessed chemical are expected to be treated as chemical waste and disposed in accordance with local government regulations. Any accidental spills of the assessed chemical during use are to be collected and disposed in accordance with local government regulations.

Some of the assessed chemical will be used in motor oils available to both commercial mechanics and DIY users. In a recent Australian survey, it was found that only 4% of households disposed of motor oil and approximately 70% of this motor oil was correctly disposed (Aither, 2013). Some vehicle lubricating oil is consumed during use, but the amount consumed is highly variable (0 - 99%) depending on the type and use of oil. Although there is some uncertainty, it may be estimated based on this data that approximately 1% (0.04 × 0.3) of all motor oil sold could be incorrectly disposed by DIY users. Accordingly, about 1% of the assessed chemical in used motor oil may be disposed of incorrectly. Release during use may also arise from drips during manual oil addition to tanks, but it is expected to be minimal.

RELEASE OF CHEMICAL FROM DISPOSAL

Residues of the assessed chemical are expected to remain in the empty drums and containers. Empty drums, commercial containers and DIY containers are expected to be disposed of to landfill. Other than small amounts of oil incorrectly disposed of, the used oil containing the assessed chemical is expected to be collected and mixed with waste oils which are to be recycled, re-refined, possibly used as low grade burner fuel or disposed of by approved waste management contractors, in accordance with local government regulations.

7.1.2. Environmental Fate

Most of the assessed chemical is expected to be disposed of by approved waste management contractors as a part of the waste oil recycling process. A minority of the assessed chemical may be released from accidental spills and leaks from vehicles and from improper disposal during DIY use. In the environment, the assessed chemical is expected to sorb to soil based on its low water solubility and its calculated log Koc value. The assessed chemical is not expected to bioaccumulate due to its extremely high log Pow (measured log Pow is > 4.7, calculated log Pow = 15.76 – 31.33). Chemicals with extremely high log Pow values are not expected to bioaccumulate as they become less bioavailable (Boethling R.S & Mackay D., 2000). Several biodegradability studies indicated that the assessed chemical is readily biodegradable (66 – 78% after 28 days using OECD TG 301B), while other studies indicated that the assessed chemical is inherently biodegradable, but not readily biodegradable (33 – 44% after 28 days using OECD TG 301F and 302C). The assessed chemical will be degraded via biotic and abiotic processes to form water and oxides of carbon. For the details of the environmental fate studies refer to Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

A Predicted Environmental Concentration (PEC) was not calculated as the proposed use pattern is expected to result in limited and diffuse dispersal from accidental leaks and will lead to minimal exposure in aquatic environments.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Acute Toxicity	LL50 > 100 mg/L (WAF)	Not harmful to fish
Fish Early Life Stage Toxicity	LL50 > 100 mg/L (WAF)	Not harmful to fish early life stage
Fish Juvenile Growth Toxicity	EL50 > 100 mg/L (WAF)	Not harmful to fish juvenile growth
Daphnia Acute Toxicity	EL50 > 100 mg/L (WAF)	Not harmful to aquatic invertebrates
Daphnia Reproduction Toxicity	EL50 > 100 mg/L (WAF)	Not harmful to aquatic invertebrate reproduction
Algal Toxicity	ErL50 > 100 mg/L (WAF)	Not harmful to algae
Inhibition of Bacterial Respiration	EC50 > 1000 mg/L	Not inhibitory to bacterial respiration
Earthworm Toxicity	LC50 > 1000 mg/kg	Not harmful to earthworms

Seed Germination and Root Elongation Toxicity	EC50 > 1000 mg/L	Not harmful to plant growth

Based on the above ecotoxicological endpoints for the assessed chemical, it is not expected to be harmful to aquatic organisms. Therefore, the assessed chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute and chronic toxicities (United Nations, 2009). The assessed chemical is also not harmful to earthworms and plant growth.

7.2.1. Predicted No-Effect Concentration (PNEC)

A Predicted No-Effect Concentration was not calculated as the assessed chemical is not harmful to aquatic organisms at its limit of water solubility. The assessed chemical is also not harmful to earthworms and plant growth.

7.3. Environmental Risk Assessment

A risk quotient (Q = PEC/PNEC) was not calculated as the assessed chemical is not harmful to aquatic organisms at the limit of water solubility and release of the assessed chemical to aquatic environment is limited based on it reported use pattern. The assessed chemical is also not harmful to earthworms and plant growth. On the basis of the low hazard and the reported use pattern, the assessed chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Vapour Pressure 5.49×10^{-10} kPa at 20 °C

Method	OECD TG 104 Vapour Pressure EC Council Regulation No 440/2008 A.4 Vapour Pressure
Remarks	Isothermal thermogravimetrical effusion method
Test Facility	Ibacon (2019a)

Water Solubility < 0.21 mg/L at 20 °C

Method	OECD TG 105 Water Solubility
Remarks	Flask Method. Water solubility value is lower than the Level of Detection (LOD)
Test Facility	Fumoprep (2020a)

Partition Coefficient (n-octanol/water) log Pow > 4.7 at 20 °C

Method	OECD TG 107 Partition Coefficient (n-octanol/water)
Remarks	Shake Flask Method; the test substance was determined by HPLC
Test Facility	Fumoprep (2020b)

Flash Point 235 °C at 101.3 kPa

Method	Similar to EC Council Regulation No 440/2008 A.9 Flash Point
Remarks	Open cup
Test Facility	SRI (2019)

Autoignition Temperature 350 °C

Method	ASTM E659
Test Facility	SRI (2019)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method
Species/Strain	Rat/Wistar
Vehicle	Corn oil
Remarks – Method	No significant protocol deviations

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	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks – Results	There were no treatment-related effects on body weights or body weight gains.
CONCLUSION	The assessed chemical is of low acute toxicity via the oral route.
TEST FACILITY	Citoxlab (2019a)

B.2. Acute Dermal Toxicity – Rat

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 402 Acute Dermal Toxicity
Species/Strain	Rat/Wistar
Type of dressing	Semi-occlusive
Remarks – Method	No significant protocol deviation

RESULTS

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

LD50	> 2,000 mg/kg bw
Signs of Toxicity – Local	No adverse local dermal signs were noted.
Signs of Toxicity – Systemic	There were no signs of systemic toxicity.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks – Results	The body weights of the animals were within the range commonly recorded for this strain and age.
CONCLUSION	The assessed chemical is of low acute toxicity via the dermal route.
TEST FACILITY	Citoxlab (2019b)

B.3. Skin Irritation – *In Vitro* EpiSkin™ Reconstituted Human Epidermis Test

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 431 In vitro Skin Corrosion: Reconstructed Human Epidermis (RHE) Test Method (2016) OECD TG 439 In vitro Skin Irritation: Reconstructed Human Epidermis Test Method (2015)

	EpiSkin™ (SM) Model
Vehicle	None
Remarks – Method	No significant protocol deviations. In a preliminary test, the test substance was shown not to directly reduce MTT. Negative control: Physiological saline (0.9% (w/v) NaCl solution) (corrosion test), PBS (irritation test) Positive Control: Glacial acetic acid (corrosion test), 5% sodium dodecyl sulphate (irritation test)

RESULTS

Corrosion test

Test material	*Mean OD_{570} of duplicate tissues*	*Relative mean viability (%)*
Negative control	1.095	100.0
Test substance	1.074	98.1
Positive control	0.002	0.2

OD = optical density

Irritation test

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean viability (%)*
Negative control	0.775	100.0
Test substance	0.778	100.5
Positive control	0.031	3.9

OD = optical density

Remarks – Results	*Corrosion:* The mean viability of the test-substance treated tissues determined after an exposure period up to 4 hours was 98.1%. *Irritation:* The mean viability of the test-substance treated tissues determined after an exposure period of 15 minutes with about 42 hours post-incubation was 100.5%. The positive and negative controls performed as expected.
CONCLUSION	Based on the mean tissue viability of > 35%, the assessed chemical was non-corrosive to the skin under the conditions of the test. Based on the mean tissue viability of > 50%, the assessed chemical is not classified as a skin irritant according to the GHS criteria.
TEST FACILITY	Citoxlab (2019c)

B.4. Eye Irritation – *In Vitro* Isolated Chicken Eye Test

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 438 Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage (2018)
Vehicle	
Remarks – Method	No significant protocol deviations Negative Control: physiological saline solution (0.9% (w/v) NaCl) Positive Control: benzalkonium chloride solution (50% (w/v) in water)

RESULTS

Test Material	*Maximal mean score for corneal opacity (ICE Class)*	*Mean score of Fluorescein retention (ICE Class)*	*Maximal corneal swelling at up to 240 min (ICE Class)*
Negative control	0.00 (I)	0.00 (I)	0% (I)
Test substance	0.00 (I)	0.33 (I)	1.7% (I)
Positive control	4.00 (IV)	3.00 (IV)	28.4% (III)

Remarks – Results All 3 endpoint scores were in Class I according to the guideline.

The positive and negative controls performed as expected.

CONCLUSION The assessed chemical does not require classification for eye irritation or serious eye damage under the conditions of the test.

TEST FACILITY Citoxlab (2019d)

B.5. Skin Sensitisation – LLNA

TEST SUBSTANCE Assessed chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain Mouse/CBA/Ca
Vehicle 2-Butanone (MEK)
Preliminary study Yes
Positive control 25% (w/v) α-Hexylcinnamaldehyde solution
Remarks – Method No significant protocol deviations

RESULTS

Concentration (% w/w)	*Number and Sex of Animals*	*Proliferative Response (DPM/lymph node)*	*Stimulation Index (test/control ratio)*
0 (vehicle control)	4F	526.4	1.0
Test Substance			
100	4F	1205.8	2.3
50	4F	950.1	1.8
25	4F	358.6	0.7
10	4F	394.6	0.7
Positive Control	4F	4417.4	8.4

Remarks – Results No mortalities or signs of systemic toxicity were noted.

The size of lymph nodes was in good correlation with the stimulation index values.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the assessed chemical.

TEST FACILITY CRL (2020a)

B.6. Combined Repeat Dose Toxicity with Reproductive/Developmental Toxicity Screening Test

TEST SUBSTANCE Assessed chemical

METHOD OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test
Species/Strain Rat/Wistar
Route of Administration Oral – gavage
Exposure Information Total exposure days: up to 29 days for males and ~68 days for females

	Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Corn oil
Remarks – Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw/day)*	*Mortality*
Control	12M/12F	0	0/24
Low Dose	12M/12F	100	0/24
Mid Dose	12M/12F	300	0/24
High Dose	12M/12F	1,000	0/24
Control Recovery	5M/5F	0	0/10
High Dose Recovery	5M/5F	1,000	0/10

Mortality and Time to Death
There were no unscheduled deaths.

Clinical Observations
No clinical signs were observed. No test substance-related changes were observed in the body weight and body weight gain parameters. No test substance-related changes were observed on food consumption.

There were no test substance-related effects on neurological assessment parameters (including animal behaviour, general physical condition, reactions to different type of stimuli, strength, landing foot splay and locomotor activity).

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No test substance-related effects on the haematology and urinalysis parameters or the serum chemistry were observed.

Effects in Organs
Parental generation
No test substance-related macroscopic abnormalities or effects on organ weights were observed. No test substance-related microscopic abnormalities were observed at necropsy.

F1 generation
No test substance-related macroscopic abnormalities were observed in F1 offspring generation examined at scheduled termination on PND13.

Reproductive effects
There were no test substance-related effects on oestrous cycles, reproductive ability, and mating or gestation indices.

Effects on pups
There were no test substance-related effects on litter data (including pup number and status at delivery and pup viability index/mortality), pup clinical observations, pup body weight data, anogenital distance and anogenital distance index, nipple/areola and pup necropsy observations.

Remarks – Results
No treatment related changes were seen in main group animals for in-life parameters, clinical pathology, necropsy or histopathology. Similarly in the recovery animals, there were no changes observed that could indicate any delayed toxicity.

No test substance-related effect on the bone marrow erythrocytes was observed when evaluated in the micronucleus test. The frequency of micronucleated polychromatic erythrocytes was comparable with the control in both males and females. The positive control group performed as expected. However, there was no reported evidence of the test substance reaching bone marrow of the tested animals.

No test substance-related effects on thyroid hormone (T4 concentration) and absolute or relative thyroid gland weights were observed in parental males and pups examined at scheduled termination on PND13.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as > 1,000 mg/kg bw/day, the highest dose tested in this study, for systemic, reproductive and developmental toxicity, based on no test substance-related effects were observed up to this dose level.

TEST FACILITY CRL (2020b)

B.7. Genotoxicity – Bacteria

TEST SUBSTANCE Assessed chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test
Plate incorporation procedure (Test 1) and Pre incubation procedure (Test 2)

Species/Strain	*Salmonella typhimurium*: TA1537, TA1535, TA100, TA98 *Escherichia coli*: WP2uvrA
Metabolic Activation System	S9 mix from phenobarbital/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 15.81 – 5000 µg/plate b) Without metabolic activation: 15.81 – 5000 µg/plate
Vehicle	Propylene Glycol + 2% Polysorbate 80
Remarks – Method	The dose selection for Test 2 was based on the toxicity observed in a preliminary test (reported as Test 1) carried out at 10 – 5000 µg/mL. Positive controls: With metabolic activation: 2-aminoanthracene Without metabolic activation: 4-nitro-o-phenylene-diamine (TA98); sodium azide (TA100, TA1535); 9-aminoacridine (TA1537); methyl-methanesulfonate (WP2 uvrA)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	≥ 1581	negative
Test 2	> 5000	> 5000	≥ 5000	negative
Present				
Test 1	> 5000	> 5000	≥ 1581	negative
Test 2	> 5000	> 5000	≥ 5000	negative

Remarks – Results	No biologically relevant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any concentration of the test substance, either with or without metabolic activation. The positive and negative controls gave a satisfactory response confirming the validity of the test system.

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

TEST FACILITY Citoxlab (2019e)

B.8. Genotoxicity – *In Vitro* Mammalian Chromosome Aberration Test

TEST SUBSTANCE Assessed chemical

METHOD OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test

Species/Strain	Chinese hamster
Cell Type/Cell Line	V79 cells

Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Vehicle	Propylene Glycol + 2% Polysorbate 80
Remarks – Method	No Significant protocol deviations. A preliminary assay carried out at 3.906-2000 µg/mL established the dose range chosen for the main experiments. Positive controls: Without metabolic activation: ethyl methanesulfonate With metabolic activation: cyclophosphamide monohydrate

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 15.625, 31.25, 62.5*, 125*, 250*	3h	20h
Test 2	0*, 15.625*, 31.25*, 62.5*, 125, 250	20h	20h
Present			
Test 1	0*, 15.625, 31.25, 62.5*, 125*, 250*	3h	20h
Test 2	0*, 15.625, 31.25, 62.5*, 125*, 250*	3h	20h

*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	> 2000	> 250	≥ 31.25	negative
Test 2	> 2000	> 250	≥ 31.25	negative
Present				
Test 1	> 2000	> 250	≥ 31.25	negative
Test 2		> 250	≥ 62.5	negative

Remarks – Results	In both main tests, no statistically significant increases in the frequency of cells with structural chromosome aberrations were observed in the presence or absence of metabolic activation. The positive and negative controls gave a satisfactory response confirming the validity of the test system.
CONCLUSION	The assessed chemical was not clastogenic to Chinese hamster V79 cells treated *in vitro* under the conditions of the test.
TEST FACILITY	Citoxlab (2019f)

B.9. Genotoxicity – *In Vitro* Mammalian Cell Gene Mutation Test

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 490 *In Vitro* Mammalian Cell Gene Mutation Test Using the Thymidine Kinase Gene (2016)
Species/Strain	Mouse
Cell Type/Cell Line	L5178Y lymphoma
Metabolic Activation System	S9 mix from phenobarbital/β-naphthoflavone induced rat liver
Vehicle	Propylene glycol + 2% Polysorbate 80
Remarks – Method	No significant protocol deviations. A preliminary assay carried out at 3.906-2000 µg/mL established the dose range chosen for the main tests. Positive controls: Without S9: 4-nitroquinoline-N-oxide With S9: cyclophosphamide monohydrate

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*
Absent			
Test 1	0, 3.906, 7.813, 15.625, 31.25, 62.5, 125, 250	3 h	2 days
Test 2	0, 15.625, 31.25, 62.5, 125, 250, 500, 1000	24 h	2 days
Present			
Test 1	0, 3.906, 7.813, 15.625, 31.25, 62.5, 125, 250	3 h	2 days
Test 2	0, 3.906, 7.813, 15.625, 31.25, 62.5, 125, 250	3 h	2 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	> 2000	> 250	≥ 250	negative
Test 2	> 2000	> 1000	≥ 125	negative
Present				
Test 1	> 2000	> 250	≥ 125	negative
Test 2		> 250	≥ 125	negative

Remarks – Results

No statistically significant or biologically relevant increases in the mutation frequency were observed, with any concentration of the test substance, either with or without metabolic activation.

The positive and negative controls gave a satisfactory response confirming the validity of the test system.

CONCLUSION

The assessed chemical was not genotoxic to mouse lymphoma L5178Y cells treated *in vitro* under the conditions of the test.

TEST FACILITY

CRL (2019)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready Biodegradability

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	Hexane
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	Due to low water solubility, the test substance was applied to glass fibre prior to testing.

RESULTS

Test Substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
6	0	6	72
10	12	10	74
14	25	14	80
21	54	21	84
28	66	28	89

Remarks – Results	The test substance reached the pass level of > 60% by the end of 28 days. The 10-day window is not considered applicable as the test substance is a UVCB. All validity criteria were met. The difference in extremes of the test replicates was 8.4% and the inorganic carbon in the blank control was 11.5 mg/L after 28 days.
CONCLUSION	The test substance is readily biodegradable.
TEST FACILITY	Arcadis (2019a)

C.1.2. Ready Biodegradability

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	Hexane
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	Due to low water solubility, the test substance was applied to glass fibre prior to testing.

RESULTS

Test Substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	6	7	67
11	18	11	73
14	25	14	76
21	47	21	81
28	71	28	87

Remarks – Results	The test substance reached the pass level of > 60% by the end of 28 days. The 10-day window is not considered applicable as the test substance is a UVCB. All validity criteria were met. The difference in extremes of the test replicates was 10.9% and the inorganic carbon in the blank control was 8.3 mg/L after 28 days.
CONCLUSION	The test substance is readily biodegradable.
TEST FACILITY	Arcadis (2019b)

C.1.3. Ready Biodegradability

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	Hexane
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	Due to low water solubility, the test substance was applied to glass fibre prior to testing.

RESULTS

Test Substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	9	7	67
11	24	11	73
14	34	14	76
21	54	21	81
28	78	28	87

Remarks – Results	The test substance reached the pass level of > 60% by the end of 28 days. The 10-day window is not considered applicable as the test substance is a UVCB. All validity criteria were met. The difference in extremes of the test replicates was 7.0% and the inorganic carbon in the blank control was 8.3 mg/L after 28 days.
CONCLUSION	The test substance is readily biodegradable.
TEST FACILITY	Arcadis (2019c)

C.1.4. Ready Biodegradability

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	Hexane
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks – Method	Due to low water solubility, the test substance was applied to glass fibre prior to testing.

RESULTS

Test Substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	10	7	67
11	20	11	73
14	28	14	76
28	78	28	87

Remarks – Results: The test substance reached the pass level of > 60% by the end of 28 days. The 10-day window is not considered applicable as the test substance is a UVCB.

All validity criteria were met. The difference in extremes of the test replicates was 10.1% and the inorganic carbon in the blank control was 8.3 mg/L after 28 days.

CONCLUSION: The test substance is readily biodegradable.

TEST FACILITY: Arcadis (2019d)

C.1.5. Ready Biodegradability

TEST SUBSTANCE: Assessed chemical

METHOD: OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum: Activated Sludge
Exposure Period: 28 days
Auxiliary Solvent: Hexane
Analytical Monitoring: Biochemical Oxygen Demand (BOD)
Remarks – Method: A toxicity test was also conducted.
The following deviation from the test guidelines was noted: the temperature exceeded the specified range of 22 ± 1°C with some readings ranging from 23.1 – 23.3°C. This is not expected to affect the validity of the test as it is a minor deviation and all the validity criteria were met for the study.

RESULTS

Test Substance		*Sodium Benzoate*		*Toxicity Control*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
7	13.7	7	80.9	7	42.4
14	28.8	14	81.3	14	44.0
21	37.1	21	87.0	21	48.1
28	43.4	28	82.4	28	49.6

Remarks – Results: The test substance did not reach the pass level, by the end of 28 days. The toxicity control reached 44% degradation by day 14 and is therefore not considered toxic to the inoculum. The 10-day window is not considered applicable as the test substance is a UVCB.

All Validity criteria were met. The difference in extremes was 18.9% at the end of the test, the oxygen demand in the inoculum blank was 28.6 mg O_2/L and the pH values were maintained between 7.27 and 7.4.

CONCLUSION: The test substance is not readily biodegradable.

TEST FACILITY: Guangdong (2019)

C.1.6. Ready Biodegradability

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	Hexane
Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks – Method	A toxicity test was also conducted.

RESULTS

Test Substance		*Sodium Benzoate*		*Toxicity Control*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
7	5	7	71	7	26
14	17.5	14	75	14	33
21	26.5	21	81	21	40
28	33.5	28	84	28	47

Remarks – Results

The test substance did not reach the pass level, by the end of 28 days. The toxicity control reached 33% degradation by day 14 and is therefore not considered toxic to the inoculum. The 10-day window is not considered applicable as the test substance is a UVCB.

All Validity criteria were met. The difference in extremes was 13% at the end of the test, the oxygen demand in the inoculum blank was 20 mg O_2/L and the pH values were maintained between 7.5 and 7.6.

CONCLUSION The test substance is not readily biodegradable.

TEST FACILITY Ibacon (2019b)

C.1.7. Inherent Biodegradability

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 302 C Inherent Biodegradability: Modified MITI (II) Test
Inoculum	Activated Sludge
Exposure Period	28 days
Auxiliary Solvent	Hexane
Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks – Method	A toxicity test was also conducted.

RESULTS

Test Substance		*Sodium Benzoate*		*Toxicity Control*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
7	15.6	7	81.6	7	53
14	34.9	14	90	14	63.2
21	37.7	21	94.6	21	69.2
28	44.5	28	96.4	28	71.1

Remarks – Results

The toxicity control reached 63.3% degradation by day 14 and is therefore not considered to be toxic to the inoculum.

All validity criteria were met. The reference substance reached 71% degradation by day 7.

CONCLUSION	The test substance is inherently biodegradable.
TEST FACILITY	Guangdong (2020a)

C.2. Ecotoxicological Investigations

C.2.1. Acute Toxicity to Fish

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-static
Species	*Brachydanio rerio*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	178 mg $CaCO_3$/L
Analytical Monitoring	Gas Chromatography with Flame Ionisation Detector (GC-FID)
Remarks – Method	A limit test at the limit of water solubility was conducted. The following deviation from the test guidelines was noted: the temperature exceeded the specified range of 21 - 25°C with temperature dropping to 20.9°C. This is not expected to affect the validity of the test as it is a minor deviation and all the validity criteria were met for the study.

RESULTS

Concentration (mg/L)		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	-	7	0	0	0	0	0
100 mg/L (Filtered WAF)	< LOD*	7	0	0	0	0	0
100 mg/L (Unfiltered WAF)	< LOD*	7	0	0	0	0	0

*The limit of detection was 0.0096mg/L

LC50	> 100 mg/L at 96 hours
NOEC (or LOEC)	100 mg/L at 96 hours
Remarks – Results	All validity criteria were met. Dissolved oxygen was maintained at > 60% of the air saturation value and analytical measurements were made on the test samples.
CONCLUSION	The test substance is not harmful to fish at the limit of water solubility.
TEST FACILITY	CRL (2020c)

C.2.2. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Semi-static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	248 mg $CaCO_3$/L
Analytical Monitoring	GC-FID
Remarks – Method	A limit test at the limit of water solubility was conducted and renewed after 24 hours. A positive control was conducted close to the test study using potassium dichromate.

RESULTS

Concentration (mg/L)		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control	-	20	0	0
100 mg/L (Filtered WAF)	< LOD*	20	0	0
100 mg/L (Unfiltered WAF)	< LOD*	20	0	2

LC50	> 100 mg/L at 48 hours
LOEC	> 100 mg/L at 48 hours
Remarks – Results	All validity criteria were met. The dissolved oxygen was maintained at > 7.2 mg/L. The reference control study showed an EC50 of 0.82 mg/L which is within the expected range.

CONCLUSION Test substance is not harmful to aquatic invertebrates at the limit of solubility.

TEST FACILITY CRL (2020d)

C.2.3. Algal Growth Inhibition Test

TEST SUBSTANCE Assessed chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L Actual: < LOD mg/L
Auxiliary Solvent	None
Analytical Monitoring	GC-FID
Remarks – Method	A limit test at the limit of water solubility was conducted. Test samples were prepared as water accommodated fractions. A positive control was conducted close to the test study using potassium dichromate.

RESULTS

Biomass		*Growth*	
ErC50 (mg/L)	*NOEL (mg/L)*	*Ey50 (mg/L)*	*NOEL (mg/L)*
>100	100	>100	100

Remarks – Results	All validity criteria were met. The control cell density increased by a factor of 66.33, the mean coefficient of variation for section-by-section specific growth was 11.83% and the coefficient of variation for the average specific growth rates was 1.13%. The reference control study showed an ErC50 of 0.82 mg/L which is consistent with previous results.

CONCLUSION Test substance is not harmful to algal growth at the limit of water solubility.

TEST FACILITY CRL (2020e)

C.2.4. Inhibition of Microbial Activity

TEST SUBSTANCE Assessed chemical

METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 10 - 1000 mg/L
Remarks – Method	As per Test guidelines. 3, 5 Dichlorophenol was used as a reference substance.
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L
Remarks – Results	All validity criteria were met. The oxygen uptake in the blank controls was 44.4 mg O_2 per mg of inoculum and the EC50 for 3, 5-Dichlorophenol was 9.61 which is within the expected range.
CONCLUSION	Test substance is not harmful to microbial respiration.
TEST FACILITY	Citoxlab (2019g)

C.2.5. Fish Early Life-Stage Toxicity Test

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 210 Fish, Early-life Stage Toxicity Test – Semi-static
Species	*Gobiocypris rarus* (Rare Minnow)
Exposure Period	34 Days
Auxiliary Solvent	None
Water Hardness	110 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	As per OECD test guidelines. The following deviation was noted: the species of fish used is not in the recommended list in the OECD test guidelines. This is not expected to affect the validity of the test.

RESULTS

Nominal test substance concentration (mg/L)	Measured Test substance concentration (mg/L)	Number exposed	Number hatched	Mortality number	Mean total length (mm) at 34 days	Mean dry weight (mg) at 34 days
Control	-	60	60	2	17.23 ± 0.21	11.0 ± 0.4
1 (WAF)	< LOD	60	60	3	17.47 ± 0.08	11.4 ± 0.3
3.2 (WAF)	< LOD	60	60	2	17.87 ± 0.08	11.8 ± 0.3
10 (WAF)	< LOD	60	60	4	17.60 ± 0.49	11.6 ± 1.0
32 (WAF)	< LOD	60	60	2	17.99 ± 0.29	12.6 ± 0.9
100 (WAF)	< LOD	60	60	4	17.76 ± 0.21	12.1 ± 0.7

NOEL	> 100 mg/L
Remarks – Results	All validity criteria were met, dissolved oxygen was maintained at > 60%, water temperature was maintained at 25°C ± 1 °C. In the control group 100% of the embryos hatched and 96.6% survival rate post hatching was achieved.
CONCLUSION	The test substance is not harmful to the early life-stage of fish.
TEST FACILITY	Guangdong (2020b)

C.2.6. Fish Early Life-Stage Toxicity Test

TEST SUBSTANCE	Assessed chemical

METHOD	OECD TG 212 Fish, Short-term Toxicity Test on Embryo and Sac-fry Stages – Semi-static
Species	*Gobiocypris rarus* (Rare Minnow)
Exposure Period	9 Days
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	As per OECD test guidelines. The following deviation was noted: the species of fish used is not in the recommended list in the OECD test guidelines. This is not expected to affect the validity of the test.

RESULTS

Nominal test substance concentration (mg/L)	Measured Test substance concentration (mg/L)	Number exposed	Number hatched	Number surviving on Day 9	Mean total length (mm)
Control	-	60	60	60	5.41 ± 0.22
100 (WAF)	< LOD	60	60	60	5.42 ± 0.14

NOEL	> 100 mg/L at 9 days
Remarks – Results	All validity criteria were met, dissolved oxygen was maintained at between 90 and 101%, water temperature was maintained at 25°C ± 1°C. In the control group 100% of the embryos hatched and 100% survival rate post hatching was achieved.

CONCLUSION The test substance is not harmful to the early life-stage of fish.

TEST FACILITY Guangdong (2020b)

C.2.7. Fish Juvenile Growth Test

TEST SUBSTANCE Assessed chemical

METHOD	State Environmental Protection Administration of China. TG 215 Fish, Juvinile Growth Test, Second Edition – Semi-static Equivalent to OECD TG 215 Fish, Juvenile Growth Test – Semi-static
Species	*Gobiocypris rarus* (Rare Minnow)
Exposure Period	28 Days
Auxiliary Solvent	None
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	GC
Remarks – Method	As per specified test guidelines. The test guidelines used differ from the OECD test guidelines only in the test species used. This is not expected to negatively impact the validity of the test.

RESULTS

Nominal test substance concentration (mg/L)	Measured Test substance concentration (mg/L)	Number exposed	Mortalities	Mean weight (mg) at 28 days	Average specific growth rate
Control	-	10	0	130 ± 22	2.72 ± 0.57
1 (WAF)	< LOD	10	0	136 ± 18	2.93 ± 0.46
3.2 (WAF)	< LOD	10	0	132 ± 12	2.80 ± 0.46
10 (WAF)	< LOD	10	0	121 ± 21	2.48 ± 0.63
32 (WAF)	< LOD	10	0	130 ± 23	2.78 ± 0.58
100 (WAF)	< LOD	10	0	126 ± 14	2.65 ± 0.39

NOEL	> 100 mg/L
Remarks – Results	All validity criteria were met. The mean body weight in the control group increased by 116% after 28 days, the dissolved oxygen content was maintained between 63% and 100% air saturation and the temperature was maintained between 22.2°C and 24.1°C.

CONCLUSION The test substance is not harmful to the juvenile growth of fish.

TEST FACILITY Guangdong (2020c)

C.2.1. Acute Toxicity to Earthworms

TEST SUBSTANCE Assessed chemical

METHOD	OECD TG 207 Earthworm, Acute Toxicity Tests
Species	*Eisenia foetida*
Duration	14 days
Concentration range	1000 mg/kg (dry wt.)
Remarks – Method	Based on a range finding test, a limit test only was conducted. The test sample was prepared by direct addition of the assessed chemical to the soil, which was then divided up into the test vessels.

RESULTS

Nominal Concentration (mg/kg dry weight)	*Total number of test earthworms*	*Exposure duration*	
		7 d	*14 d*
		Cumulative mortality (%)	*Cumulative mortality (%)*
Control	40	0	0
1000	40	0	0

Remarks – Results	The validity criterion was met.

CONCLUSION The assessed chemical is not harmful to earthworms.

TEST FACILITY Guangdong (2020d)

C.2.2. Chronic Toxicity to Aquatic Invertebrates

TEST SUBSTANCE Assessed chemical

METHOD	OECD TG 211 *Daphnia magna* Reproduction test
Species	*Daphnia magna*
Exposure Period	21 d
Auxiliary Solvent	None
Analytical Monitoring	GC
Remarks – Method	As per OECD test guidelines. No deviations were noted. A limit test only was conducted.

Nominal Test substance loading (mg/L)	Measured test substance concentration (mg/L)	Number of parent daphnia	Survival (% parental generation)	Mean no. offspring per female
Control	-	10	100	164 ± 9
10	< LOD	10	100	167 ± 20

NOEC	≥ 10 mg/L
EC50	> 10 mg/L
Remarks – Results	All validity criteria were met. The amount of living offspring in the control group was > 60.

CONCLUSION	The test substance is not harmful to invertebrate reproduction at the limit of water solubility.
TEST FACILITY	Guangdong (2020e)

C.2.3. Seed Germination/Root Elongation Toxicity Test

TEST SUBSTANCE	Assessed chemical
METHOD	OPPTS 850.4200 Seed Germination/Root Elongation Toxicity Test
Species	*Lycopersicon esculentum* (tomato), *Cucumis sativis* (cucumber), *Lactuca sativa* (lettuce), *Phaseolus radiates* L. (mung bean), *Brassica oleracea* (cabbage), *Citrullus lanatus* (watermelon), *Brassicaceae brassica* (mustard leaf), *Oryza sativa* (rice), *Daucus carota* (carrot), *Zea mays* (corn).
Exposure Period	Test terminated once 65% of the control cohort had germinated and developed roots ≥ 20 mm long.
Auxiliary Solvent	Hexane
Analytical Monitoring	GC
Concentration Range	Nominal: 50, 100, 500, 1000 mg/L Actual: 39.8, 78.4, 320, 808 mg/L
Remarks – Method	No deviations from test guidelines.
RESULTS	
EC50	> 1000 mg/L for germination and root elongation inhibition.
Remarks – Results	Germination rates at the nominal concentration of 1000 mg/L were ≥ 60% in all ten seed types tested. The root development inhibition rate was ≤ 33.6%. Therefore, the EC50 of both seed germination and root development inhibition are > 1000 mg/L All validity criteria were met. Seed moisture content was ≤ 8.0%, the germination percentage in the solvent control was ≥ 73.3% and the glassware and artificial substrates were not polluted.
CONCLUSION	Test substance is not harmful to plant growth.
TEST FACILITY	Guangdong (2020f)

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