File No: STD/1559

September 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Alkenes, C_{10-16} α-, reaction products with (6*E*)-7, 11-dimethyl-3-methylene-1,6,10-dodecatriene, hydrogenated

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1559	Penrite Oil Company	Alkenes, C_{10-16} α-, reaction products with (6*E*)-7,11-dimethyl-3-methylene-1,6,10-dodecatriene, hydrogenated	Yes	≤ 10,000 tonnes per annum	Lubricant oil

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is 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 recommended hazard classification is presented in the table below.

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

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R65 Harmful: may cause lung damage if swallowed

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

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

Environmental risk assessment
On the basis of the 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:
  - Aspiration Toxicity Category 1: H304 – May be fatal if swallowed and enters airways

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

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Enclosed, automated processes, where possible
  - Exhaust ventilation, if appropriate

- 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:
  - Respiratory protection if ventilation is inadequate
  - Coveralls and impervious gloves

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

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

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

Public Health

- As liquid hydrocarbons are included in Schedule 5 of the SUSMP, any labelling and/or packaging requirement for products containing the notified chemical, which are available to the public, should be adhered to.

Disposal

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

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from lubricant oil, 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.

(Material) Safety Data Sheet
The (M)SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Penrite Oil company (ABN: 25 005 001 525)
88 Lewis Road
WANTIRNA SOUTH VIC 3152

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: water solubility, partition coefficient, dermal toxicity, soil adsorption and bioaccumulation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2014), Europe (2014)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
NovaSpec Renewable White Oil
NovaSpec Base Oil
'x' cSt Base Oil (where 'x' = 3 to 16)
NovaSpec 450

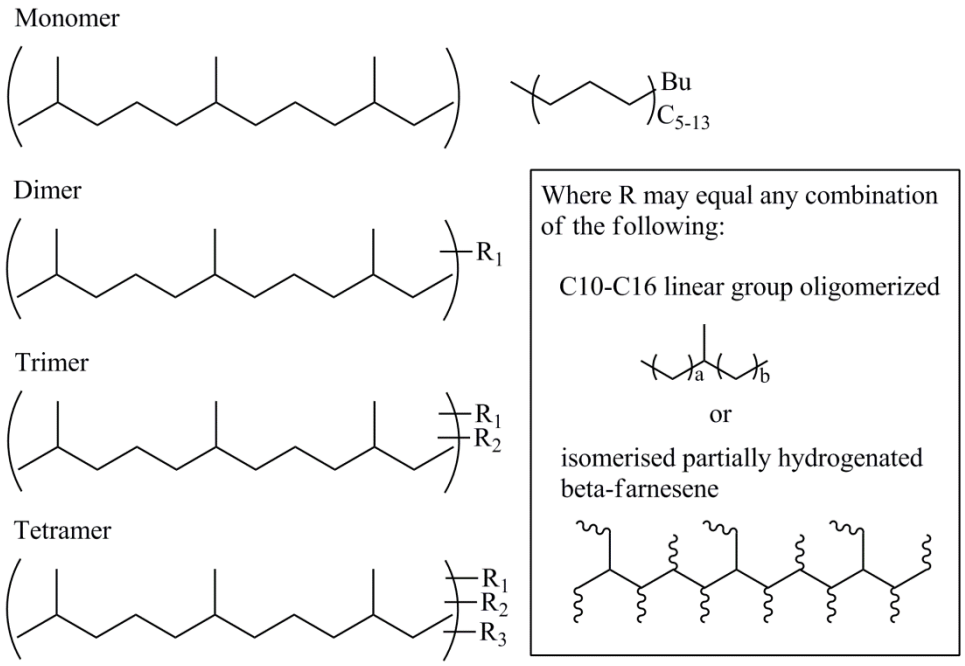
CAS NUMBER
1481694-12-5

CHEMICAL NAME
Alkenes, C_{10-16} α-, reaction products with (6*E*)-7,11-dimethyl-3-methylene-1,6,10-dodecatriene, hydrogenated

OTHER NAMES
Highly branched isoparaffinic hydrocarbons
Partially hydrogenated β-3,7,11-trimethyldodeca-1,3,6,10-tetraene, reaction products with linearC10-C16 α olefin, hydrogenated

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



MOLECULAR WEIGHT
≥ 212 Da

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

3. COMPOSITION

DEGREE OF PURITY
100%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: colourless liquid

Property	Value	Data Source/Justification
Pour Point	-39 °C 101.3 kPa	Measured
Boiling Point	216 - 686°C at 101.1 kPa	Measured
Density	820 kg/m^3 at 25 °C	Measured
Vapour Pressure	1.22 kPa at 37.8 °C	Measured
Kinematic Viscosity	3-16 mm^2/s at 100 °C 13-141 mm^2/s at 40 °C	Measured
Water Solubility	1 × 10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains no readily hydrolysable functionalities and hence is not expected to hydrolyse under normal environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	log Pow > 5.31 at 20 °C	Calculated

Adsorption/Desorption	log K_{oc} = 4.28-16.73	Calculated using KOWWIN v1.68 (US EPA, 2011)
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	226 °C at 101.3 kPa	Measured
Flammability	Not flammable	Measured
Autoignition Temperature	245 °C	Measured
Explosive Properties	Not explosive	Estimated
Oxidising Properties	Not oxidising	Estimated

DISCUSSION OF PROPERTIES
The above mentioned physico-chemical properties are the product NovaSpec Base Oil. For full details of tests on physical and chemical properties, refer to Appendix A.

The viscosity range provided is estimated at 100 °C. According to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* and the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) substances with viscosity < 20.5 mm^2/s at 40 °C should be classified for aspiration hazard. The notified chemical will be imported into Australia in 3 different grades based on viscosity. Therefore, depending on the viscosity of the notified chemical (i.e. where the viscosity is < 20.5 mm^2/s at 40 °C), it should be classified as hazardous. See Section 6.2 for further details regarding the health hazard classification.

Reactivity
The notified chemical is expected to be stable under normal conditions of use.

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported in to Australia as a raw material (100% concentration) in bulk for reformulation, and as a component of end use products (10 – 99.5% concentration by weight). The notified chemical will be imported into Australia in three different grades, based on viscosity. The different grades will have the same constituents but differ in the constituent levels as shown in the following table:

*Product viscosity grade**	*Monomer fraction (%) Average Mw≈204*	*Dimer fraction (%) Average Mw≈420*	*Trimer fraction (%) Average Mw≈630*	*Tetramer fraction (%) Average Mw≈860*
3 to 4 mm^2/s	0-4	95-99	0-10	0
7 to 10 mm^2/s	0	0-10	60-90	0-30
12 to 16 mm^2/s	0	0-10	20-40	50-80

* at 100 °C

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	200	1,000	5,000	10,000	10,000

PORT OF ENTRY
Melbourne, Portland

IDENTITY OF MANUFACTURER/RECIPIENTS
Penrite Oil Company

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in to Australia in ISO tanks and intermediate bulk containers as the raw material. The notified chemical may also be imported in small packages as finished lubricating products (10 – 99.5% by weight). The notified chemical will be transported by road to the reformulation site where it will be

stored. After reformulation, it will be packaged and distributed by road and rail to professionals and retailers. The containers for the finished lubricant products would range in size from 1 – 5 L containers for public consumers and 50 – 200 L containers for industrial and professional use.

USE
The notified chemical will be used as a component of lubricants at 10 to 99.5% by weight in a wide range of applications. These applications include automotive lubricants, metal working fluids/rolling oils, rubber production and processing, polymer processing, functional fluids and laboratory chemicals and general consumer lubricants.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia, but will be reformulated after importation.

Reformulation
At the site of reformulation the notified chemical will be transferred to the blending machine using flexible transfer hoses and pumps, which will be flushed before disconnection. Spear pumps may also be used in the transfer of the notified chemical from drums. There may also be some instances transfer of the notified chemical into the blending facilities will be done manually when the storage containers are small. The blending process will occur at > 50 °C in either blending tanks or via continuous static mixture, and is expected to be in enclosed automated systems with adequate ventilation. The finished products containing the notified chemical will be tested for quality control purposes and then packaged in sizes dependant on the end use via automated filling processes.

End use
The finished lubricants containing the notified chemical at 10-99.5% will be used to replace and/or top-up lubricants in engines, industry equipment and for general lubricant purposes.

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	≤ 4	100
Quality control samplers	1	100
Cleaning and maintenance	≤ 8	52
Industrial / Professional end users	≤ 1	200

EXPOSURE DETAILS
Occupational exposure to the notified chemical may occur via the dermal, ocular and inhalation routes when handling the notified chemical during transport, reformulation and end use.

Transport and storage workers are not expected to be exposed to the notified chemical at up to 100% concentration except in the unlikely event of an accidental spill or rupture of containers.

During reformulation workers may be exposed to the notified chemical at up to 99.5% concentration during transfer, blending, sampling and cleaning and maintenance of equipment. Exposure is expected to be minimised through the use of enclosed systems with exhaust ventilation and through the use of personal protective equipment (PPE) such as overalls, gloves, safety goggles and respiratory protection, as anticipated by the notifier in the application dossier.

Professional end users may be exposed to the notified chemical during the use of formulated products containing the notified chemical at concentrations up to 99.5%. Again exposure may be minimised through the use of personal protective equipment (PPE) such as overalls, gloves and safety goggles.

6.1.2. Public Exposure

Products containing the notified chemical at up to 99.5% concentration will be available to public for use as lubricants in engines, industry equipment and for general lubricant purposes. There is a potential for dermal and accidental ocular and oral exposure to the notified chemical by the public, however such exposure is expected to be less frequent than for professional end users.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation (in vitro)	non-irritating
Skin irritation (in vitro)	non-irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28-54 days.*	NOAEL > 1,000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration test in V79 cells	non genotoxic
Genotoxicity – *in vitro* mammalian cell gene mutation test in mouse lymphoma L5178Y TK+/- cells	non genotoxic
Genotoxicity – *in vivo* micronucleus assay*	non genotoxic
Rat, reproductive and developmental toxicity*	NOAEL = 1,000 mg/kg bw/day

* – studies conducted together

Toxicokinetics, metabolism and distribution.

No toxicokinetics, metabolism and distribution studies were provided. Based on the low molecular weight (< 500 Da) there is potential for the notified chemical to cross the gastrointestinal track by passive diffusion or to be dermally absorbed. The notified chemical belongs to class of chemicals known as white mineral oils which have traditionally been used in ointments and cosmetics for topical application. Studies carried out on white mineral oils show that they are poorly absorbed (Zesch and Bauer, 1985).

Acute toxicity.

The notified chemical is of low toxicity via the oral route with LD50 > 2,000 mg/kg bw. No acute dermal and inhalation toxicity data were provided on the notified chemical. Based on studies conducted on white mineral oils (Nash *et al.* 1996), the notified chemical is expected to have low toxicity via the dermal route. The notified chemical will be imported at various viscosities and when it has a kinematic viscosity less than 20.5 mm^2/s at 40 °C would be classified as aspiration hazard (category 1) according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

Irritation and sensitisation.

In vitro skin irritation and corrosion studies carried out on the notified chemical suggest the chemical is non-irritant. Rabbit eye irritation studies classify the chemical as slightly-irritating.

An LLNA study on the notified chemical indicated that the notified chemical is not a skin sensitizer.

Repeated dose toxicity.

A combined repeated dose toxicity study with a reproduction /developmental toxicity screening test was conducted by gavage in rats with the notified chemical. The test substance concentrations selected were 100, 300 and 1,000 mg/kg bw/day. The NOAEL was determined to be > 1,000 mg/kg bw/day based on a lack of adverse effects at all dose levels.

Mutagenicity/Genotoxicity.

In a bacterial reverse mutation test, a chromosome aberration test in V79 cells and a gene mutation test in mouse lymphoma L5178Y TK+/- cells the notified chemical was non-mutagenic and non-genotoxic. Additionally in an *in vivo* erythrocyte micronucleus test in rats the notified chemical was not clastogenic.

Toxicity for reproduction.
A reproduction/developmental toxicity screening test was conducted as part of repeated dose toxicity in rats using the notified chemical at 100, 300 and 1,000 mg/kg bw/day concentrations. The study reported a NOEL of 1000 mg/kg bw/day based on an absence of effects at all concentrations.

Health hazard classification
Based on the available information, the notified chemical is 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 recommended hazard classification is presented in the following table.

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

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R65: Harmful: may cause lung damage if swallowed

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Studies on the notified chemical show it to be of low toxicity with slight eye irritation the only effect seen. However, when the notified chemical has a kinematic viscosity less than 20.5 mm^2/s at 40 °C it would be classified as an aspiration hazard (category 1).

Dermal, ocular and perhaps inhalation exposure (from mist or aerosols) to the notified chemical may occur during handling, storage, reformulation and end-use of the products containing the notified chemical at up to 99.5% concentration. Workers handling the notified chemical in large quantities are of most concern. The use of PPE including coveralls, goggles and impervious gloves by workers would reduce the exposure levels. In addition as proposed by the notified, the use of enclosed well ventilated systems would further minimise the risk. While the notified chemical is considered to be hazardous if swallowed and entering into airways, ingestion of the chemical is unlikely under the occupational settings described. Therefore, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health
The public may be exposed to the notified chemical at up to 99.5% concentration during replacing or top-up of automotive lubricants. Liquid hydrocarbons are included in Schedule 5 of the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP), with packaging/labelling requirements for products available to the public.

Public exposure will be brief and infrequent and generation of aerosols or mist is not expected during the exposure. Therefore, the risk to public health from the use of the notified chemical is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported into Australia as end use products or neat chemical for further reformulation. The application in Australia will be as base fluids or additives for lubricant oils and greases mainly used for industrial application. Significant release of the notified chemical to the environment is not expected during transport and storage except in the unlikely event of accidental spills or leaks.

Any notified chemical spilled during reformulation is expected to be contained with bunds and either reclaimed or sent to on-site waste treatment facilities. At the on-site waste treatment facilities, residues of the notified chemical will be separated from the aqueous waste stream by the American Petroleum Industry (API) process.

As a result of this treatment, greater than 90% of the notified chemical is estimated to be removed. The aqueous waste undergoes further treatment involving pond aeration and biological treatment before being released to the sewage system. The remaining non-aqueous waste is expected to be disposed of according to local regulations, which is most likely to landfill. Therefore, the accidental release from reformulation of the notified chemical and finished oils is unlikely to be significant.

RELEASE OF CHEMICAL FROM USE
The finished products containing the notified chemical will be used as a component of lubricants and greases. The oils will also be used as hydraulic and compressor fluids. Release during its use may come from spills when pouring lubricants into the machinery or leaks from the machinery, which is expected to be negligible.

RELEASE OF CHEMICAL FROM DISPOSAL
After reformulation, empty import drums containing residues of the notified chemical (0.1% of the total import volume) are expected to be steam cleaned, with the residual waste sent to on-site wastewater treatment facilities. Assuming 0.1% of the notified chemical remains in the empty drums after use, 10,000 kg/yr (10,000 tonnes/yr × 0.1%) of the notified substance will be sent to the on-site waste treatment. It is estimated that greater than 90% of the notified chemical may be removed during waste treatment processes. Therefore, the amount of the notified chemical released to sewer from the cleaning of empty drums is estimated to be 1000 kg/yr . The wastewater will be further treated at the sewage treatment plants. Therefore, the release of the notified chemical to surface waters is expected to be limited from the cleaning of empty drums.

The majority of the formulated lubricants containing the notified chemical will be used as lubricant products. At the end of life, the fluids will be drained from the machinery for disposal. The main method of disposal will be by recycling or thermal decomposition.

The notified chemical may be released to the environment during disposal of waste or used oils. Oil products containing the notified chemical will be poured into engines by automotive manufacturers, service centres or by do-it-yourself (DIY) consumers. A survey by the Australian Institute of Petroleum (AIP, 1995) indicates that of the annual sales of engine oils in Australia, 60% of oils are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly (e.g. oil recycling or incineration). Assuming this is the case, negligible release of the notified chemical should result from these professional activities. The remaining 14% of oil is removed by DIY consumers. In these cases, some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. It was estimated that DIY activities account for 7 - 10% of the unaccounted used oil (Meinhardt, 2002).

According to a survey tracing the fate of used lubricating oil in Australia (Snow 1997), only approximately 20% of used oil removed by DIY consumers is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. In a worst case scenario involving the 14% of used oil removed by DIY consumers, up to 0.7% (= 14% × 5%) of the total import volume of the notified chemical may enter the aquatic environment via disposal to stormwater drains. Therefore, the amount of the notified chemical released to the aquatic environment from disposal of used oil due to DIY consumers is expected to be 70 tonnes/yr In addition to this, considering the unknown fate of some of the oil used by DIY consumers, a small proportion may also be disposed of to the sewer. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified chemical in neat concentrations is unlikely except as a result of transport accidents.

7.1.2. Environmental Fate

The notified chemical exceeded a biodegradation degree of > 87% within the 28 day test period. It is expected to be biodegradable in the environment. For the details of the environmental fate studies please refer to Appendix C. Based on the structure and characteristics of the notified chemical, it is expected to have low water solubility. Given its low molecular weight (< 300), the presence of a hydrophobic segment, and the lack of charged functional groups, it may have potential for bioaccumulation. However, due to its expected low water solubility and biodegradability in the environment, the notified chemical is not expected to be bioavailable to aquatic organisms.

The majority of the notified chemical is expected to be consumed during use or be recycled or thermally decomposed during metal reclamation/disposed of to landfill. In either way, the notified chemical is expected to decompose into water and oxides of carbon.

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 > 100 mg/L (WAF)	Not harmful to fish
Daphnia Toxicity	48 h EL50 > 100 mg/L (WAF)	Not harmful to aquatic invertebrates
Inhibition of Bacterial Respiration	EC50 >1000 mg/L	Not toxic to bacterial respiration
Earthworm	EC50 > 1000 mg/kg	Not toxic to earthworm

The toxicity data to fish, daphnia and alga in the table above suggest that the notified chemical is not harmful to aquatic organisms up to the limit of water solubility. The notified chemical is considered to be readily biodegradable. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is not expected to be harmful to fish, invertebrates and algae on an acute or long term basis and is not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

It is not necessary to calculate the Predicted No-Effect Concentration (PNEC) since no significant release of the notified chemical is expected from the proposed use pattern.

7.3. Environmental Risk Assessment

The risk quotient (RQ = PEC/PNEC) has not been calculated. The notified chemical is not harmful to the aquatic environment. The notified chemical is not expected to persist in the environment due to its biodegradability. Therefore, based on the assessed use pattern and low potential for aquatic exposure, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Pour Point -39 °C

Method	ASTM D97 – 11 Standard Test Method for Pour Point of Petroleum Products
Remarks	The test material was NovaSpec 450
Test Facility	SRI (2012)

Relative Density 820 kg/m^3 at 25 °C

Method	ASTM D 4052 – 96 (Reapproved 2002) Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter
Remarks	The test material was NovaSpec 450
Test Facility	Novvi (date unknown)

Viscosity 3-16 mm^2/s at 100 °C
13-141 mm^2/s at 40 °C

Method	ASTM D7042 – 11 Standard Test Method for Dynamic Viscosity and Density of Liquids by Stabinger Viscometer (and the Calculation of Kinematic Viscosity)
Test Facility	Novvi (2015)

Vapour Pressure 1.22 kPa at 37.8 °C

Method	ASTM D5191 – 12 Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method)
Test Facility	SRI (2013)

Water Solubility 1×10^{-4} g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method
Test Facility	BMG (2014)

Flash Point 226 °C at 101.3 kPa

Method	ASTM D92 – 05 Standard Method for Flash and Fire Points by Cleveland Open Cup Tester
Remarks	The test material was NovaSpec 450
Test Facility	SRI (2012)

Autoignition Temperature 245°C

Method	ASTM E659 – 14 Standard Test Method for Autoignition Temperature of Liquid Chemicals
Remarks	The test was conducted on NovaSpec base oil
Test Facility	SRI (2014)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure.
Species/Strain	Rat/Wistar (RccHan™:WIST)
Vehicle	Arachis oil BP
Remarks - Method	No significant deviations from the OECD guidelines. A sighting test was initially performed with one female test rat at dose levels of 300 mg/kg and 2,000 mg/kg bw. Subsequently, four additional female rats were dosed at 2,000 mg/kg bw.

RESULTS

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

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	All animals survived the study and showed expected bodyweight gains over the study period.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Harlan (2013a)

B.2. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 431 In vitro Skin Corrosion - EPISKIN™ Reconstructed Human Epidermis (RHE) Test Method
Vehicle	None
Remarks - Method	No significant deviations from the OECD guidelines.

In a pre-test, the test substance did not reduce MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolim bromide]. The test substance (50 µL) was applied to the tissues in duplicate. Following exposure periods of 3 minutes (37 °C; test 1), 1 hour (37 °C; test 2) and 4 hours (37 °C; test 3), the tissues were rinsed, treated with 2.0 mL of MTT solution (0.3 mg/mL) and then incubated at 37 °C for 3 hours.

Positive and negative controls were run in parallel with the test substance:
- Negative control (NC): 0.9% sodium chloride solution
- Positive control (PC): Glacial acetic acid

RESULTS

Test material	*Test 1 (3 minute exposure period)*		*Test 2 (1 hour exposure period)*		*Test 3 (4 hour exposure period)*	
	Mean OD_{562} of duplicate tissues	*Relative mean viability (%)*	*Mean OD_{562} of duplicate tissues*	*Relative mean viability (%)*	*Mean OD_{562} of duplicate tissues*	*Relative mean viability (%)*

Negative control	-	-	-	-	0.868	100*
Test substance	0.997	114.9	0.933	107.3	1.045	120.4
Positive control	-	--	-	-	0.031	3.6

OD = optical density
* The mean viability of the negative control tissues is set as 100%.

Remarks - Results: The positive and negative controls gave satisfactory results, confirming the validity of the test system.

CONCLUSION: The notified chemical was non-corrosive to the skin under the conditions of the test.

TEST FACILITY: Harlan (2013b)

B.3. Irritation – skin (in vitro)

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 439 In vitro Skin Irritation - EPISKIN™ Reconstructed Human Epidermis (RHE) Test Method

Vehicle: –

Remarks - Method: No significant deviations from the OECD guidelines.

In the pre-test, the test substance was found not to reduce MTT. For the skin irritation test, the test substance (10 µL) was applied to the tissues in triplicate. Following an exposure period of 15 minutes at room temperature, the tissues were rinsed and then incubated in fresh medium at 37 °C for 42 hours. The tissues were then treated with MTT and incubated at 37 °C for 3 hours.

Positive and negative controls were run in parallel with the test substance:
- Negative control (NC): Phosphate Buffered Saline Dulbecco's (PBS) with Ca^{++} and Mg^{++}
- Positive control (PC): sodium dodecyl sulphate (SDS)

RESULTS

Test material	*OD_{562} of triplicate tissues (Mean ± SD)*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	0.811 ± 0.046	100.0*	5.7
Test substance	0.859 ± 0.066	105.9	8.2
Positive control	0.076 ± 0.018	9.4	2.2

OD = optical density; SD = standard deviation
*The mean viability of the negative control tissues is set as 100%.

Remarks - Results: The positive and negative controls gave satisfactory results, confirming the validity of the test system.

CONCLUSION: The notified chemical was non-irritating to the skin under the conditions of the test.

TEST FACILITY: Harlan (2013c)

B.4. Irritation – eye

TEST SUBSTANCE: Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 7 days
Remarks - Method No significant deviations from the OECD guidelines.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period (7 days)*
	1	2	3			
Conjunctiva: redness	1.00	0.66	0.66	1	< 7 days	0
Conjunctiva: chemosis	1.00	0.33	0.66	1	< 7 days	0
Conjunctiva: discharge	0.00	0.33	0.33	1	< 48 hours	0
Corneal opacity	0.00	0.00	0.00	1	< 24 hours	0
Iridial inflammation	0.00	0.00	0.00	0	-	0

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

Remarks - Results Minimal conjunctival irritation was noted in all treated eyes 1 hour after treatment. Two treated eyes appeared normal at the 72 hour observation and one treated eye appeared normal on the 7 day observation.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Harlan (2014)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
Species/Strain Mouse/CBA/CaOlaHsd (female)
Vehicle Butanone
Preliminary study Yes
Positive control Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using 85% α-Hexylcinnamaldehyde, tech.
Remarks - Method No significant deviations from the OECD guidelines.

In a preliminary study, one mouse was treated by daily applications of 25 µL of undiluted test substance to the dorsal surface of each ear for 3 consecutive days. The mouse was observed for 3 more days after application. No signs of systemic toxicity and local irritation were noted.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	4	596.50	-
10	4	1153.03	1.93
25	4	1028.34	1.72
100	4	1404.55	2.35

Remarks - Results No local or systemic toxicity or notable weight changes were observed.

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

TEST FACILITY Harlan (2013d)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	Rat/Crl:WI
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days (male; 14 days premating and 14 days mating/post mating) or 40-54 days (female; 14 days pre-mating, up to 12 days mating, 21-24 days gestation and 4 days post-partum) Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Polyethylene glycol (PEG) 400 + 0.2% polysorbate 80
Remarks - Method	No significant deviations from the OECD guidelines. A mammalian erythrocyte micronucleus test was also conducted in parallel on the high dose and control groups.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	12 M & 12 F	0	0
low dose	12 M & 12 F	100	0
mid dose	12 M & 12 F	300	0
high dose	12 M & 12 F	1,000	0
control recovery	5 M & 5 F	0	0
high dose recovery	5 M & 5 F	1,000	0

Mortality and Time to Death

All test animals survived until the scheduled necropsy.

Clinical Observations

Red discharge from the eyes was observed in one male rat from the low dose group on day 20. Vaginal prolapse was noted on one female from low dose group from day 20 which progressed to the prolapse of uterus, in one female from mid dose group from day 29 and a prolapse of uterus was seen in one female from high dose group from day 38. The females from mid and high dose group showing prolapse also showed piloerection. Due to the random and occasional nature, the signs were considered incidental by the study authors.

Neurological assessment did not reveal any test substance related adverse effects.

There was a statistically significant decrease (↓69.3%) in mean body weight gain in recovery group female animals on days 36-42. =The study authors considered the decrease to be incidental with no toxicological relevance. There were no toxicologically relevant changes in ford consumption.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

High dose group animals had significantly higher percentage of monocytes when compared to controls. However, this was ascribed to lower control values rather than the effect of treatment as when comparing the values to historical mean control values the difference was not statistically significant.

In males, statistically significant lower than control albumin and total protein group mean values were noted in the mid and high dose groups, however the values were also comparable to historical control values.

There were no significant differences in the urinalysis parameters between the control and treatment groups.

Effects in Organs

Significantly higher absolute (21%) and relative (19% to body 20% to brain) weights of adrenal glands were noted in male rats from the high dose group when compared to the control group. However, no associated

clinical pathology or pathology effects were observed.

Reproductive/Developmental Effects

There were no treatment related effects on reproductive parameters. There were no increases in mortality or adverse developmental parameters in the F1 generation. The body weight and body weight gain of the F1 animals were not significantly different between control and treatment groups, with any slight variations considered to be incidental by the study authors.

Micronucleus Test

No statistically significant increase in the number of micronuclei were noted in either male of female animals in the high dose group when compared to the control animals.

Remarks – Results

The test substance was not clastogenic under the conditions of the *in vivo* mammalian erythrocyte micronucleus test.

There was no difference between the control and test substance treated groups with regards to reproductive ability or in the mating or gestational indices. The administration of test substance to parental generation did not cause mortality or any adverse effects in the F1 generation.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 1,000 mg/kg bw/day for female rats and 300 mg/kg bw/day for male rats in this study, based on the increase in absolute and relative weights or adrenal gland in male rats exposed to high dose.

The No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day for general toxicity, reproduction toxicity and for the development of first generation off-springs.

TEST FACILITY CiToxLAB (2015a)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure and pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98 & TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 50-5,000 µg/plate b) Without metabolic activation: 50-5,000 µg/plate
Vehicle	Tetrahydrofuran
Remarks - Method	No significant deviations from the OECD guideline.

RESULTS

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

Remarks - Results The vehicle and positive controls gave satisfactory results confirming the sensitivity of the strains and validity of S9 mix.

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

TEST FACILITY Harlan (2013e)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Species/Strain Chinese hamster
Cell Type/Cell Line V79 cell line
Metabolic Activation System S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Vehicle PEG400 + 0.2% polysorbate 80
Remarks - Method No significant deviations from the OECD guidelines.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	156.25*, 312.5*, 625*, 1250, 2500, 5000	3 h	20 h
Test 2	156.25*, 312.5*, 625*, 1250, 2500, 5000	20 h	28 h
Present			
Test 1	156.25, 312.5*, 625*, 1250*, 2500, 5000	3 h	20 h
Test 2	156.25, 312.5*, 625*, 1250*, 2500, 5000	3 h	28 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation at the end of treatment*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	≥ 156.25	Negative
Test 2	> 5,000	> 5,000	≥ 156.25	Negative
Present				
Test 1	> 5,000	> 5,000	≥ 156.25	Negative
Test 2	> 5,000	> 5,000	≥ 156.25	Negative

Remarks - Results All the positive control chemicals used in the test induced marked increases in the frequency of mutant colonies thus confirming the activity of the S9-mix and the sensitivity of the test.

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

TEST FACILITY CiToxLAB (2015b)

B.9. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
Species/Strain Mouse
Cell Type/Cell Line Lymphoma L5178Y TK +/-
Metabolic Activation System S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver
Vehicle PEG 400 + 0.2% polysorbate 80
Remarks - Method No significant deviations from the OECD guidelines.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	156.25, 312.5, 625, 1250, 2500, 5000	3 h	3 days	14 days

Test 2	156.25, 312.5, 625, 1250, 2500, 5000	24 h	3 days	14 days
Present				
Test 1	156.25, 312.5, 625, 1250, 2500, 5000	3 h	3 days	14days
Test 2	156.25, 312.5, 625, 1250, 2500, 5000	3 h	3 days	14 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	> 5,000	> 5,000	≥ 156.25	Negative
Test 2	> 5,000	> 5,000	≥ 156.25	Negative
Present				
Test 1	> 5,000	> 5,000	≥ 156.25	Negative
Test 2	-	> 5,000	≥ 156.25	Negative

Remarks - Results: All the positive control chemicals used in the test induced marked increases in the frequency of mutant colonies thus confirming the activity of the S9-mix and the sensitivity of the test.

CONCLUSION: The notified chemical was not clastogenic to Mouse Lymphoma L5178Y TK +/- cells treated in vitro under the conditions of the test.

TEST FACILITY: CiToxLAB (2015c)

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: CO2 Evolution Test. .
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	8.3	7	42.3
14	36	14	85.7
21	61.4	21	94.3
28	77.9	28	97

Remarks - Results	All validity criteria were met. The positive control, sodium benzoate, reached 86% biodegradation after 14 days, thus confirming suitability of inoculum and test conditions. The test substance did not reach the pass level of 60% for ready biodegradability in the test within the 10-d window and, therefore, cannot be termed as readily biodegradable. However, the test substance reached the pass level of 60% after 28 days.
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	BMG (2012)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated Sludge
Exposure Period	28 Days
Auxiliary Solvent	None Reported
Analytical Monitoring	Biochemical oxygen demand (BOD)
Remarks - Method	The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*

28	26	7	77
		14	90

Remarks - Results: All validity criteria were met. The positive control reached the pass level of 77 % on day 7 (criterion: >40%) and the pass level of 90 % on day 14 (criterion > 65%). The notified chemical is considered "not readily biodegradable" as a plateau of approx. 26 % degradation was reached after 28 days.

CONCLUSION: The notified chemical is not readily biodegradable

TEST FACILITY: CERI (2015)

C.1.3. Ready biodegradability

TEST SUBSTANCE: Notified 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: The test was conducted according to the above mentioned OECD test guidelines. No significant deviations from the test guidelines were reported.

RESULTS

Notified chemical (biological oxygen demand)		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	3.8	7	76.6
17	34.3	17	82.1
28	49	28	79.9

Remarks - Results: All validity criteria for the test were satisfied. The reference control reached the pass level of 60% within 6-7 days. The toxicity control showed no evidence for inhibition of the microbial inoculum.

The biodegradation degree of the notified chemical did meet the 10-day window criterion for readily biodegradability. The test substance reached 49% biodegradation in 28 days. Therefore, the notified chemical is not considered readily biodegradable according to the OECD (301 F) guideline.

CONCLUSION: The notified chemical is considered readily biodegradable.

TEST FACILITY: GDMC (2014a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 203 Fish, Acute Toxicity Test - Static test
- Species: Zebra-fish (*Brachydanio rerio*)
- Exposure Period: 96 hours
- Auxiliary Solvent: None
- Water Hardness: 246 mg $CaCO_3$/L
- Analytical Monitoring: None
- Remarks – Method: Tested in accordance with the test guideline without significant deviation from the protocol. Good Laboratory Practices (GLP) was followed.

Due to the limited water solubility of the notified chemical, water accommodated fraction (WAF) was used in the test. The test solution was prepared by direct addition of the notified chemical into laboratory dilution water, follow by agitation for 24 hours. The non-dissolved test material was removed by filtration through a fine (0.22 μm) filter to give the 100 % v/v saturated solution. As only limit test was carried out, further dilution of stock solution was not performed.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control		7	0	0	0	0
100		7	0	0	0	0

LC50	>100 mg/L at 96 hours. (WAF)
NOEC	100 mg/L at 96 hours. (WAF)
Remarks – Results	All validity criteria for the test were satisfied. Since a WAF method was used to prepare the treatment solutions, the endpoints were based on the nominal loading rates used to prepare the WAF solutions. No mortality of was observed throughout the test.

CONCLUSION The notified chemical is not harmful to fish.

TEST FACILITY CiToxLAB (2014a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test - Static test

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	Gas chromatography
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. Due to the limited water solubility of the notified chemical, water accommodated fraction (WAF) was used in the test. The test solution was prepared by direct addition of the notified chemical into laboratory dilution water, follow by agitation for 24 hours. The non-dissolved test material was removed by filtration through a fine (0.22 μm) filter to give the 100 % v/v saturated solution. As only limit test was carried out, further dilution of stock solution was not performed.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control		20	0	0
100		20	0	0

EC50	>100 mg/L at 48 hours (WAF)
NOEC	100 mg/L at 48 hours (WAF)

Remarks - Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates.
TEST FACILITY	Harlan (2013f)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Algal Growth Inhibition Test.
Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not given
Analytical Monitoring	Not provided
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. Due to the limited water solubility of the notified chemical, water accommodated fraction (WAF) was used in the test. The test solution was prepared by direct addition of the notified chemical into laboratory dilution water, follow by agitation for 24 hours. The non-dissolved test material was removed by filtration through a fine (0.22 µm) filter to give the 100 % v/v saturated solution. As only limit test was carried out, further dilution of stock solution was not performed.

RESULTS

Biomass (72 h)		*Growth (72 h)*	
E_yL50 (mg/L)	*NOE_yL (mg/L)*	*E_yL50 (mg/L)*	*NOE_yL (mg/L)*
> 100	100	> 100	100

Remarks - Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to algae up to the limit of its water solubility.
TEST FACILITY	CiToxLAB (2014b)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 10, 100, 1000 mg/L
Remarks – Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L

Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not expected to inhibit microbial respiration
TEST FACILITY	Harlan (2013g)

C.2.5. Earthworm Acute toxicity test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 207 Earthworms, Acute toxicity test
Remarks - Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed. One test group of 1000 mg/kg dry soil was designed
RESULTS	14 d LC50 > 1,000 mg/kg dry soil.
Remarks - Results	All validity criteria for the test were satisfied. The 14 d LC50 was out of the tested concentration range (> 1,000 mg/kg dry weight).
CONCLUSION	The notified chemical is not toxic to earthworm.
TEST FACILITY	GDMC (2014b)

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