File No: LTD/1663

September 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Tribotecc-BIS 83

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

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
LTD/1663	The Shell Company of Australia Limited	Tribotecc-BIS 83	ND*	≤ 1 tonne per annum	Lubricant for machines

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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

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

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

Recommendations

REGULATORY CONTROLS

(Material) Safety Data Sheet

- The (M)SDS of the product containing the notified chemical provided by the notifier should be amended as follows:
  - The (M)SDS should be prepared according to the appropriate Safe Work Australia Code of Practice

CONTROL MEASURES
Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering control to minimise occupational exposure to the notified chemical as introduced in the lubricating grease:
  - Use automated application systems

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the lubricating grease:
  - Avoid direct skin and eye contact with the grease
  - Avoid inhalation of vapours

- 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 as introduced in the lubricating grease:

- Impervious gloves
- Safety glasses
- Protective clothing
- Respiratory protection if volatile decomposition products are likely to be present.

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

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

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

Disposal

- The notified chemical should be disposed of to landfill.

Storage

- The following precaution should be taken by the notifier regarding storage of the notified chemical:
  - Avoid storing the notified chemical with acids and oxidising reagents

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical;
- additional information on the genotoxicity of the chemical has become available;
- the chemical in powder form is to be imported into Australia for reformulation.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from being a lubricant for machines, or is likely to change significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet

The (M)SDS of the notified chemical and products containing the notified chemical provided by the notifier were 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
The Shell Company of Australia Limited (ABN: 46 004 610 459)
8 Redfern Road
HAWTHORN EAST VIC 3001

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less 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: hydrolysis as a function of pH, vapour pressure, partition coefficient and adsorption/desorption.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
Canada (2011)
EU (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Tribotecc-BIS 83

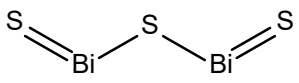
CAS NUMBER
1345-07-9

CHEMICAL NAME
Bismuth sulfide (Bi_2S_3)

OTHER NAME(S)
Dibismuth trisulfide
Bismuth sesquisulfide
Bismuth(3+) sulphide

MOLECULAR FORMULA
Bi_2S_3

STRUCTURAL FORMULA



MOLECULAR WEIGHT
514.16 Da

ANALYTICAL DATA
Reference X-ray diffractometry (XRD) spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY > 97%

HAZARDOUS IMPURITIES	None identified
NON HAZARDOUS IMPURITIES (> 1% by weight)	None identified
ADDITIVES/ADJUVANTS	None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Dark grey odourless powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Cannot be determined	Measured, decomposition / sublimation starts at approximately 600°C.
Boiling Point	Not determined	Decomposes before boiling
Density	6,812 kg/m^3 at 20°C	Measured
Vapour Pressure	Not applicable	Melting point > 300°C
Water Solubility	0.41 × 10^{-6} g/L at 20°C	Measured
Hydrolysis as a Function of pH	Not determined	Does not contain hydrolysable functionality and has limited water solubility
Partition Coefficient (n-octanol/water)	Not determined	Cannot be determined as the notified chemical is an inorganic substance that has limited water solubility
Adsorption/Desorption	Not determined	Not expected to be mobile in soils or sediment based on its limited water solubility
Dissociation Constant	Not determined	Does not contain dissociable functionality
Surface Tension	72.5 mN/m at 20°C	Measured
Particle Size	Inhalable fraction (< 100 μm): 92.4% Respirable fraction (< 10 μm): 29.8%	Measured
Flammability	Not flammable solid	Measured
Explosive Properties	Not explosive	Measured, decomposition enthalpy = -131.2 J/g; Contains no functional groups that would imply explosive properties
Oxidising Properties	Not tested	Contains no functional groups that would imply oxidative properties
Self-Reactivity	Not self-reactive	Measured
Self-Heating Properties	Not self-heating	Measured

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

Reactivity
The notified chemical is expected to be stable under normal conditions of use. It is incompatible with strong oxidising agents and strong acids.

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of finished lubricating grease at concentrations ranging from 0.5% to 5%.

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

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

PORT OF ENTRY
Brisbane

IDENTITY OF RECIPIENT
The Shell Company Australia Limited

TRANSPORTATION AND PACKAGING
The finished lubricating grease containing the notified chemical will be imported in 190 kg drums via sea ports.

USE
The grease containing the notified chemical will be used for lubricating open gears and pinions in heavy industrial machines, mainly mining excavators and shovels.

OPERATION DESCRIPTION
The finished grease containing the notified chemical at 0.5% to 5% will be imported in 190 kg drums by ship in containers, unloaded by forklifts from containers at the warehouse and stored under cover. The grease containing the notified chemical is to be decanted from drums into bulk grease hoppers in the sizes of approximately 1.2 - 1.5 tonnes for use at the end use sites. The decanting activity will be carried out in dedicated grease plant equipped with drum pumps for handling heavy gear grease.

A total loss automated lubrication injector system fed by on-board tank containing the grease with the notified chemical will be used on the end use sites. No manual handling will be required during the replenishment of the grease tanks and the application of the grease to the machines.

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)*
Transportation and storage	1.2	50
Grease filling	3	50

EXPOSURE DETAILS
Transport and storage
The finished grease containing the notified chemical up to 5% will be imported in 190 kg drums. Workers may come into contact with the notified chemical only in the event of accidental package breakage. The workers involved in the operation will have the potential for dermal and ocular exposure to the notified chemical at concentrations up to 5%. Appropriate personal protective equipment (PPE) including coverall, chemical goggles and impervious gloves are expected to be used to reduce any potential of exposure.

Preparing grease hoppers
The lubricating grease containing the notified chemical at concentrations from 0.5 to 5% will be decanted to the grease hopper in the sizes of 1.2 - 1.5 tonnes. During the operation, the workers will have the potential for dermal and ocular exposure to the notified chemical up to 5%. Inhalation exposure is not expected. PPE including protective clothing, impervious gloves and chemical glasses should be worn by the workers.

End-use
Workers at the end-use sites applying the grease containing the notified chemical to the machineries would have potential for dermal and ocular exposure to the notified chemical up to 5%. Inhalation exposure is not

expected. PPE including protective clothing, impervious gloves and chemical glasses should be applied. The automated grease injector system will further reduce the exposure potential for the notified chemical.

6.1.2. Public Exposure

The finished product containing the notified chemical is intended for industrial application only. The public is not expected to have potential exposure to the notified chemical except in the event of accidental release of the chemical in the public area during transportation.

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
Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation (*in vitro*)	Non-irritating
Rabbit, eye irritation	Slightly irritating
Mouse, skin sensitisation – local lymph node assay	Inadequate evidence of sensitisation
Rat, repeat dose oral toxicity – 14 days	NOEL = 300 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – *in vitro* mammalian cell gene mutation test	Equivocal result*
Rat, reproductive and developmental toxicity	NOAEL = 1,000 mg/kg bw/day

* Especially at concentrations with precipitation

Toxicokinetics, metabolism and distribution.

No data were available for the notified chemical. Based on the use patterns provided, the main route of exposure is expected to be dermal absorption. However, based on the very low water solubility, the dermal absorption potential of the chemical is likely to be low.

Acute toxicity.

Acute oral and dermal toxicity studies of the notified chemical did not show signs of adverse effects and the notified chemical was considered of low toxicity. No acute inhalation data was available.

Irritation and sensitisation.

Skin irritation

An *in vitro* skin irritation test using reconstituted human epidermis cells did not show signs of irritation for the notified chemical. However, in an acute dermal toxicity study, rat skin treated with the chemical at 2,000 mg/kg bw showed slight erythema that was reversible.

Eye irritation

The notified chemical showed slight conjunctival irritation effects to rabbit eyes that were reversible in 24 hours.

Skin sensitisation

A mouse local lymph node assay (LLNA) on the notified chemical did not reveal adequate evidence of skin sensitisation potential. The stimulation index (SI) exceeded the threshold of 3 for sensitisation only at the lowest level tested (25%) and no dose response trend was seen. Based on the available data, there is not a strong concern for skin sensitisation.

Repeated Dose Toxicity.

In a 14-day dose range finding study, rats administrated by gavage with the notified chemical at concentrations of up to 1,000 mg/kg bw/day did not show any toxicologically significant clinical effects. Statistically significant higher mean concentrations of inorganic phosphorous (Pi) were noted in females treated with 1,000 mg/kg bw/day; lower alkaline phosphatase (ALP) was also noted in this group. However, the significance of this finding over the longer term is unknown. At necropsy of the test animals, no effects of the notified chemical on examined organs were noted. Male rats treated with 1,000 mg/kg bw/day of the notified chemical were observed to have a slight depression of body weight gain compared to controls; however this effect was not noted when males in a reproductive study (discussed below) were treated with the same regime for 43 days. Based on the lowered body weight in the 14-day study, a conservative NOEL of

300 mg/kg bw/day was determined by the study authors.

Mutagenicity/Genotoxicity.
The notified chemical showed no evidence of mutagenicity in a bacterial reverse mutation study.

In an *in vitro* mammalian cell gene mutation test using mouse lymphoma cells, the notified chemical showed equivocal evidence of clastogenicity, predominantly at concentrations with precipitation present in the medium. In the study there were significant increases in mutant colonies, particularly in the presence of metabolic activation, and precipitation at some doses. However the global evaluation factor (GEF) criterion for a positive result was exceeded only in one of three tests. The study authors suggested that the precipitate may have been carried on to later stages of the study, increasing the exposure of the cells to the notified chemical. Based on the study, the clastogenicity potential of the notified chemical is unclear.

Toxicity for reproduction.
In a reproduction/developmental toxicity study, rats administrated orally with the notified chemical at up to 1,000 mg/kg bw/day did not show any adverse effects on weight, clinical signs, or at necropsy in either the parental or F1 generational animals. There were no treatment related effects on any reproductive performance parameters, on gestation length or delivery parameters for damns, or semiology parameters for males. Additionally, no abnormalities in offspring development were noted up to sacrifice on post-partum Day 4. Based on the lack of any significant effects, a NOAEL of 1,000 mg/kg bw/day was established for both systemic and reproductive/developmental toxicity.

Reactivity
The MSDS for the notified chemical notes that sulphur dioxide may be formed in contact with strong oxidising agents, and hydrogen sulphide may be formed in contact with strong acids.

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the toxicological data submitted, the notified chemical may be a slight irritant to skin and eyes. This potential is likely to be reduced by the low concentration of introduction and use (≤ 5%). It is unclear whether the chemical has clastogenic potential.

When handling the finished grease containing the notified chemical up to 5% during decanting and end use, dermal and ocular exposure of workers to the notified chemical may occur. Inhalation exposure is not expected. Avoidance of direct skin and eye contact through the use of PPE, safe work practices and automated application systems would reduce worker exposure. When used in the proposed manner, the risk of the notified chemical to the health of the workers is not expected to be unreasonable.

Hazardous decomposition products (hydrogen sulphide or sulphur dioxide) may be formed in contact with strong acids or oxidising agents. Precautions to avoid exposure would be needed in any conditions where such decomposition products are formed.

6.3.2. Public Health
The finished product containing the notified chemical is intended for industrial application only. The public is not expected to have potential exposure to the notified chemical except for the event of accidental release of the chemical in the public area during transportation. Based on the use patterns provided, the risk of the notified chemical to the health of the public is not expected 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 not be manufactured or reformulated in Australia. Therefore, release to the environment is not expected from these activities. Releases to the environment may occur following accidental spills during import, transport or storage of products containing the notified chemical at up to 5%. Any notified chemical that is spilled is expected to be adsorbed onto a suitable material and collected for disposal in accordance with industry and local regulations.

Residues of the notified chemical in empty import containers (up to 0.01 % of the total import volume of the notified chemical) are expected to be disposed of according to industry and local regulations.

RELEASE OF CHEMICAL FROM USE

The product containing the notified chemical is expected to be used as lubricating grease for open gears and pinions in industrial machinery. The notified chemical in the product is not expected to be released to the environment during use. Accidental spills are expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations. Therefore, limited release of the notified chemical is expected during use.

RELEASE OF CHEMICAL FROM DISPOSAL

The notifier expects that the notified chemical will be consumed during use. Any application equipment or wastes containing the notified chemical are expected to be cleaned or disposed of according to industry and local regulations. Therefore, limited release of the notified chemical to the environment is expected from disposal.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified chemical is expected to be disposed of according to industry and local regulations. Because of this, limited release of the notified chemical to the environment is expected. Disposal of the notified chemical may result in its release to landfill. If this occurs, the notified chemical is not expected to be mobile due to its limited water solubility. Standard biodegradation tests are not applicable to metal-containing inorganic substances such as the notified chemical, because the methods are based on carbon oxidation. However, the notified chemical is not expected to be biodegradable as it is a small inorganic salt with limited water solubility. If the notified chemical is accidently released to sewer, as a solid with a density greater than water it has the potential to settle and be removed during primary treatment in sewage treatment plants (STP). Therefore, it is not expected to be released to surface waters in the sewage effluent. While metals have the potential to bioaccumulate in organisms, the significance of measure for bioaccumulation for metal-containing inorganic substances is difficult to interpret (Adams and Chapman, 2007) and computer models are unsuitable. However, the notified chemical is not expected to have the potential for bioaccumulation based on its limited release to the aquatic compartment and limited bioavailability. Any notified chemical in surface waters would be expected to disperse and eventually settle on the floor of the aquatic compartment.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) for the notified chemical has not been calculated as limited release to the aquatic environment is expected during reformulation, use and disposal.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LC50 > 100 mg/L	Not harmful
Daphnia Toxicity (48 h)	EC50 > 100 mg/L	Not harmful
Algal Toxicity (72 h)	E_rC50 > 100 mg/L	Not harmful
Inhibition of Bacterial Respiration (3 h)	EC50 > 1000 mg/L	Not inhibitory to microbial activity

The available measured data indicates that the notified chemical is not expected to be harmful to aquatic organisms on an acute basis. Therefore, the notified chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

As no significant adverse effects were observed in any of the ecotoxicity tests submitted, it was not considered appropriate to predict a no-effect concentration (PNEC), as this concentration would be significantly greater than the notified chemicals' solubility in water.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not calculated because the calculation of PEC and PNEC were not considered meaningful. Based on the anticipated lack of aquatic exposure and the absence of any observed adverse ecotoxicological effects, the notified chemical is not expected to pose an unreasonable risk to the environment based on the assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point Cannot be determined

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	The test was performed using differential scanning calorimetry. Decomposition and/or sublimation of the test substance started at approximately 600°C. Because of simultaneous thermal effects no melting point could be determined during the test.
Test Facility	AQura GmbH (2011)

Density 6,812 kg/m^3 at 20°C

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	
Test Facility	AQura GmbH (2011)

Water Solubility 0.41×10^{-6} g/L at 20°C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. It was anticipated that the water solubility of the test substance would be limited. It could also not be coated on an inert carrier that is needed for the column elution method; therefore the flask method was used. Atomic Absorption Spectroscopy (AAS) was used to determine the concentration of the test substance in the test solution.
Test Facility	STZ Angewandte und Umwelt-Chemie (2012)

Surface Tension 72.5 mN/m at 20°C

Method	OECD TG 115 Surface Tension of Aqueous Solutions. EC Council Regulation No 440/2008 A.5 Surface Tension.
Remarks	Concentration: 18 mg/L Method: ring tensiometer
Test Facility	AQura GmbH (2011)

Particle Size

Method ISO 13320
USP 429

Range (µm)	*Mass (%)**
< 10	29.83
< 100	92.37
≥ 100	7.63

* Average of 3 measurements

Remarks	d_{10} = 2.99 µm, d_{50} = 20.6 µm, d_{90} = 80.1 µm (average of 3 measurements using laser diffraction spectrometer)
Test Facility	AQura GmbH (2011)

Solid Flammability Not flammable solid

Method	Transport of Dangerous Goods, Manual of Tests and Criteria, 5th Edition, UN 2009.
Remarks	Not classified as a flammable solid
Test Facility	AQura GmbH (2011)

Explosive Properties Not explosive

Method	Transport of Dangerous Goods, Manual of Tests and Criteria, 5th Edition, UN 2009.
Remarks	The test substance contains no chemical groups associated with explosive properties.

	Thermal stability test using the Differential Scanning Calorimeter (DSC) showed an enthalpy of -133.4 J/g for the decomposition of the test substance.
Test Facility	AQura GmbH (2011)

Self-Reactivity Not self-reactive

Method	Transport of Dangerous Goods, Manual of Tests and Criteria, 5th Edition, UN 2009.
Remarks	Thermal stability test using the Differential Scanning Calorimeter (DSC) showed an enthalpy of -133.4 J/g for the decomposition of the test substance.
Test Facility	AQura GmbH (2011)

Self-Heating Properties Not self-heating

Method	Transport of Dangerous Goods, Manual of Tests and Criteria, 5th Edition, UN 2009.
Remarks	Initiation of the exothermic reaction was observed at 352.8°C.
Test Facility	AQura GmbH (2011)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Crl:(WI)Br
Vehicle	Sunflower oil (Helianthi annui oleum raffinatum)
Remarks - Method	No significant protocol deviation was noted. Each test animal received a single dose (2,000 mg/kg bw) oral administration by gavage.

RESULTS

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

LD50	> 2,000 mg/kg bw
Signs of Toxicity	None noted
Effects in Organs	None noted
Remarks - Results	

CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	TOXI-COOP ZRT (2013a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test. EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal) – Limit Test.
Species/Strain	Rat/Crl:(WI)Br
Vehicle	None (test material was pulverised and moistened with water)
Type of dressing	Semi-occlusive.
Remarks - Method	The dose levels for the main Limit test were chosen on the basis of a preliminary range-finding test. The observation time was 7 days in the preliminary test and 14 days in the main test.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Preliminary 1	2 F	2,000	0/2
Preliminary 2	2 F	300	0/2
Preliminary 3	2 F	50	0/2
Preliminary 4	2 F	5	0/2
Main	5 M/5 F	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	Reversible slight skin erythema was observed on the treatment sites.
Signs of Toxicity - Systemic	No significant toxicity signs were noted. One female rat treated at 2,000 mg/kg bw showed slight body weight loss in the first week, however it was considered likely due to individual variation.
Effects in Organs	None noted

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

TEST FACILITY TOXI-COOP ZRT (2013b)

B.3. Irritation – skin (*in vitro*)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 439 *In vitro* Skin Irritation: Reconstructed Human *Epidermis* Test Method
EC Commission Regulation No 751/2009 B.46 *In Vitro* Skin Irritation: Reconstructed Human Epidermis Model Test
EpiSkin SOP, Version 1.8 (February 2009), ECVAM Skin Irritation Validation Study: Validation of the EpiSkin test method 15 min - 42 hours for the prediction of acute skin irritation of chemicals

Vehicle None. The test substance was applied directly to the Epidermal surface.

Remarks - Method EPISKIN Model was used. The notified chemical was applied to moistened skin, and was used in powder form as supplied. The test protocol indicates that it was not ground before application.

Positive control: sodium dodecyl sulphate (5%)
Negative control: phosphate buffered saline
Exposure: 15 min at room temperature

RESULTS

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	0.916	100	5.66
Positive control	0.070	8	3.49
Test substance	0.923	101	2.18

OD = optical density; SD = standard deviation

Remarks - Results

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

TEST FACILITY TOXI-COOP ZRT (2012e)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White

Number of Animals 3

Observation Period 72 h

Remarks - Method 100 mg of the test substance was directly applied to the each test eye of the animals.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0	0	1	< 24 h	0

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: chemosis	0	0	0	0	N/A	0
Conjunctiva: discharge	0	0	0	1	< 24 h	0
Corneal opacity	0	0	0	0	N/A	0
Iridial inflammation	0	0	0	0	N/A	0

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

Remarks - Results: The test substance caused slight conjunctival irritant effects that were reversible within 24 hours.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: TOXI-COOP ZRT (2012f)

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

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Commission Regulation No 440/2008 B.42 Skin Sensitisation: Local Lymph Node Assay

Species/Strain: Mouse/CBA/Ca

Vehicle: Dimethyl sulfoxide (DMSO)

Remarks - Method: The test item was suspended in the vehicle, as it was insoluble in all other vehicles tested. For 100% concentration 1 g of the test substance was suspended in the vehicle to a final volume of 1 mL.

Positive control (concurrent): α-Hexylcinnamaldehyde (HCA) dissolved in acetone:olive oil (4:1 v/v) mixture (AOO)

Erythema scores were noted in the preliminary and main studies. Ear thickness was recorded for the preliminary study only.

Number of animals: 5 in each group

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (DMSO control)	1126.3 ± 191.7	1.0
25	3711.5 ± 827.3	3.3**
50	2349.9 ± 296.7	2.1**
100	2464.7 ± 1066.7	2.2*
Positive Control		
0 (AOO control)	946.3 ± 623.5	1.0
25	13518.3 ± 7689.7	14.3

* Significant increase compared to the DMSO control ($P < 0.05$)
** Significant increase compared to the DMSO control ($P < 0.01$)

Remarks - Results: The observed proliferation values were statistically significantly increased in all test item treated groups compared to the vehicle control and the SI value observed at 25 % was above the threshold value of 3. However, no dose-response was noted in the study.

No erythema or increase in ear thickness was noted.

The positive control showed a high increase in stimulation index, as expected.

	The cause of the increased proliferation at the lowest tested level - 25%, is not known.
CONCLUSION	There was inadequate evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	TOXI-COOP ZRT (2013c)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	14-day dose range finding study; similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Wistar: Hsd.Brl.Han
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 14 days Dose regimen: 7 days per week Post-exposure observation period: None
Vehicle	Sunflower oil (Helianthi annui oleum raffinatum)
Remarks - Method	Animals were euthanized by exsanguination one day after the last treatment.

RESULTS

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

Mortality and Time to Death

No mortality was observed in any of the groups during the study.

Clinical Observations

No significant test substance related clinical effects were noted in any of the groups during the study. The mean body weight was slightly but statistically significantly less than the control group in male animals treated with 1,000 mg/kg bw/day on Day 7 due to lower mean body weight gain during week 1. The difference in weight recovered in the second week with no significant difference between control and high dose males on day 13. Additionally, there were no differences between the treated and control female animals in the mean body weight and body weight gain values during the study. Food consumption was not effected by treatment in any dose group.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were no significant test substance-related changes in the examined haematological and clinical chemistry parameters in male or female animals at any dose level.

Statistical significance was noted for the shorter mean prothrombin time in male animals treated at 100 mg/kg bw/day. Slight, but statistically significant differences were detected in the mean percentage of neutrophil granulocytes (NEU) and lymphocytes (LYM) in female animals treated at 1,000 and 100 mg/kg bw/day. The mean platelet count (PLT) was slightly higher in female animals at 1,000 mg/kg bw/day.

The mean activity of aspartate aminotransferase (AST) was slightly higher in male animals at 100 mg/kg bw/day. Statistically significant differences were noted for lower alkaline phosphatase (ALP) in female animals treated at 1,000 and 100 mg/kg bw/day and higher mean concentration of inorganic phosphorous (Pi) at 1,000 mg/kg bw/day.

The study authors considered that above mentioned statistical significances should be treated as low likelihood

of toxicological significance as all were within historical ranges except for elevated Pi.

Effects in Organs
Specific microscopic alterations indicative of test substance effects were not observed in the organs and tissues at any dose level. No test substance effect was observed relating to the weight of the examined organs.

Remarks – Results
Under the conditions of the study, the notified chemical caused a slight depression of body weight and body weight gain in male rats treated at 1,000 mg/kg bw/day

CONCLUSION
The No Observed Effect Level (NOEL) was established as 300 mg/kg bw/day in this study, based on the body weight effect in the male rats.

TEST FACILITY TOXI-COOP ZRT (2013d)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD OECD TG 471 Bacterial Reverse Mutation Test
EC Commission Regulation No 440/2008 B.13/14 Mutagenicity – Reverse Mutation Test Using Bacteria
Plate incorporation (Test 1) and pre-incubation (Test 2) methods

Species/Strain *S. typhimurium*: TA1535, TA1537, TA98 and TA100
E. coli: WP2uvrA

Metabolic Activation System S9 from phenobarbital/β-naphthoflavone induced rat liver

Concentration Range in Main Test
a) With metabolic activation: 15.8 - 5,000 µg/plate
b) Without metabolic activation: 15.8 - 5,000 µg/plate

Vehicle Dimethyl sulfoxide (DMSO)

Remarks - Method Dosage levels were determined in a pre-experiment using TA98 and TA100 strains.

Positive controls:

Without metabolic activation	
4-nitro-1,2-phenylene-diamine (NPD)	TA98
Sodium azide (SAZ)	TA100 and TA1535
9-aminoacridine (9AA)	TA1537
Methyl-methanesulfonate (MMS)	WP2uvrA
With metabolic activation	
2-aminoanthracene (2AA)	All strains

RESULTS

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

Remarks - Results Sporadic increases in revertant rate were observed in both main experiments, with all increases less than two folds. However, there was no significant dose-response in relation with the test substance. The positive controls all showed significant increases in revertants, confirming the validity of the test method.

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

TEST FACILITY TOXI-COOP ZRT (2013e)

B.8. Genotoxicity – *in vitro*

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 *In vitro* Mammalian Cell Gene Mutation Test.
EC Commission Regulation No 440/2008 B.17 Mutagenicity - *In vitro* Mammalian Cell Gene Mutation Test.

Species/Strain Mouse
Cell Type/Cell Line Lymphoma/L5178Y/TK$^{+/-}$
Metabolic Activation System S9
Vehicle Dimethyl sulfoxide (DMSO)
Remarks - Method Small and large colony mutant frequencies were not calculated in the study.

Positive controls:
Without metabolic activation - 4-Nitroquinoline-N-oxide (NQO)
With metabolic activation - Cyclophosphamide (monohydrate, CP)

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	15.8, 50, 158, 500, 1581, 5000	3 h	2 d	11 - 13 d
Test 2	50, 100, 200, 400, 600, 800	24 h	2 d	11 - 13 d
Present				
Test 1	15.8, 50, 158, 500, 1581, 5000	3 h	2 d	11 - 13 d
Test 2	158, 500, 1580, 2500, 4000, 5000	3 h	2 d	11 - 13 d
Test 3	1500, 1700, 1900, 2100, 2300	3 h	2 d	11 - 13 d

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 50	≥ 50	≥ 1,581	Equivocal*
Test 2	≥ 250	≥ 100	> 800	Negative
Present				
Test 1	≥ 50	≥ 1,581	≥ 5,000	Equivocal*
Test 2	≥ 250	≥ 1,580	≥ 2,500	Equivocal*
Test 3	≥ 100	≥ 1,500	≥ 2,100	Equivocal*

* High concentrations with precipitation of the test substance showed significant mutation rate increase.

Remarks - Results In test 1 with and without metabolic activation, and in test 2 with metabolic activation, precipitation of the test substance at high concentrations was associated with statistically significant increases of mutation frequency. However, the increases did not meet the Global Evaluation Factor (GEF) criterion for a positive response, except for dosages ≥ 2,500 μg/mL in test 2 with metabolic activation. In a confirmatory study with metabolic activation over a narrower dose range (Test 3), statistically significant increases in mutation frequency were seen at several dose levels and precipitate was seen at ≥ 2,100 μg/mL, however none of the results met the GEF criterion for a positive response. The authors stated that the high mutation rates in dosages with precipitate were likely due to the presence of test substance in the media during the

expression and selection period that was carried over from treatment, thus increasing the exposure time to the test substance.

The positive controls performed as expected in the study.

CONCLUSION The notified chemical gave an equivocal clastogenic response under the conditions of the test.

TEST FACILITY TOXI-COOP ZRT (2013f)

B.9. Reproduction/developmental toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 421 Reproduction/Developmental Toxicity Screening Test
Species/Strain Rat/Wistar: Hsd.Brl.Han
Route of Administration Oral – gavage
Exposure Information Exposure days and observation period:
Continuous daily exposure and observation until necropsy;
Male - 43 days; female - 43 or 49 days
Vehicle Sunflower oil (Helianthii annui oleum raffinatum)
Remarks - Method The dose setting, 100, 300 and 1,000 mg/kg bw/day, was based on findings obtained in previous 14-day oral gavage dose range finding study.

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
1	12 M/12 F	0	0/12
2	12 M/12 F	100	0/12
3	12 M/12 F	300	0/12
4	12 M/12 F	1,000	0/12

Mortality and Time to Death
There was no mortality noted at any dose level.

Effects on Parental generation
No significant test substance related differences were observed between the control and treatment groups for general toxicity, body weight or reproductive performance for either sex. In males, seminology parameters were normal for all dose groups. In females, no adverse effects were noted in pregnancy duration or any delivery outcomes of dams in any dose group.

No statistically significant differences in organ weights were noted at any dose level, nor any abnormalities noted at necropsy. No abnormal histopathological effects of the test substance were observed in any organ tested (brain, testes and epididymides for males; uterus, vagina, ovaries, pituitary for females).

Effects on F1 generation
No adverse effects of the test substance on mortality or development of offspring including clinical signs, body weight and necropsy findings were noted during the observation period and up until sacrifice (between postnatal Days 0 and 4).

Remarks - Results
Alopecia in one dam treated with 300 mg/kg bw/day was observed as a dermal alteration from gestational day 14 up to the end of the observation period.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 1,000 mg/kg bw/day in this study, based on the highest dose tested in the study.

TEST FACILITY TOXI-COOP ZRT (2013g)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static. EC Council Regulation No 440/2008 C.1 Acute Toxicity for Fish – Static.
Species	Zebrafish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	237 mg $CaCO_3$/L
Analytical Monitoring	Not conducted due to the limited water solubility of the test substance and low level present in the test solution.
Remarks – Method	The test was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. The test solution was prepared using a water accommodated fraction (WAF). A supersaturated solution (approximately 100 mg/L test substance) was prepared using the test substance and approximately 10 minutes of ultrasonic dispersion. The solution was shaken for 24 hours. The non-dissolved test substance was removed by filtration through a 0.22 µm filter.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality*				
		1 h	*24 h*	*48 h*	*72 h*	*96 h*
100	10	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	All relevant test validity criteria were met.

CONCLUSION	The notified chemical is not harmful to fish up to its limit of solubility
TEST FACILITY	TOXI-COOP ZRT (2012a)

C.1.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test - Static. EC Council Regulation No 440/2008 C.2 Acute Toxicity for Daphnia - Static
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	225 mg $CaCO_3$/L
Analytical Monitoring	Not conducted due to the limited water solubility of the test substance and low level present in the test solution.
Remarks - Method	The test was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. The test solution was prepared using a water accommodated fraction (WAF). A supersaturated solution (approximately 100 mg/L test substance) was prepared using the test substance and approximately 10 minutes of ultrasonic dispersion. The solution was shaken for 24 hours. The non-dissolved test substance was removed by filtration through a 0.22 µm filter.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h	*48 h*
100	4 × 5	0	0

LC50	> 100 mg/L at 24 hours > 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	All relevant test validity criteria were met.

CONCLUSION The notified chemical is not harmful to aquatic invertebrates up to its limit of solubility

TEST FACILITY TOXI-COOP ZRT (2012b)

C.1.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 201 Alga, Growth Inhibition Test.
EC Council Regulation No 440/2008 C.3 Algal Inhibition Test.

Species	*Pseudokirchneriella subcapitata*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Not conducted due to the limited water solubility of the test substance and low level present in the test solution.
Remarks - Method	The test was conducted according to test guidelines using good laboratory practice (GLP) with no significant deviations. The test solution was prepared using a water accommodated fraction (WAF). A supersaturated solution (approximately 100 mg/L test substance) was prepared using the test substance and approximately 10 minutes of ultrasonic dispersion. The solution was shaken for 24 hours. The non-dissolved test substance was removed by filtration through a 0.22 µm filter.

RESULTS

Biomass		*Growth*	
E_yC50 mg/L at 72 h	*NOEC mg/L at 72 h*	*E_rC50 mg/L at 72 h*	*NOEC mg/L at 72 h*
> 100	100	> 100	100

Remarks - Results All relevant test validity criteria were met.

CONCLUSION The notified chemical is not harmful to algae up to its limit of solubility

TEST FACILITY TOXI-COOP ZRT (2012c)

C.1.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test
EC Commission Regulation No 440/2008 C.11 Biodegradation: Activated Sludge Respiration Inhibition Test

Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range	Nominal: 1,000 mg/L
Remarks – Method	The test was conducted according to test guidelines using good laboratory

	practice (GLP) with no significant deviations. The test substance at nominal concentration of 1000 mg/L was added directly to the test vessel and the test vessel was subsequently inoculated.
RESULTS	
IC50	> 1,000 mg/L
NOEC	1,000 mg/L
Remarks – Results	All relevant test validity criteria were met.
CONCLUSION	The notified chemical is not inhibitory to microbial activity
TEST FACILITY	TOXI-COOP ZRT (2012d)

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