File No: STD/1544

March 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Pentanoic acid, 5-(dimethylamino)-2-methyl-5-oxo-, methyl ester (Rhodiasolv PolarClean)

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:

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

TABLE OF CONTENTS

SUMMARY 3
CONCLUSIONS AND REGULATORY OBLIGATIONS 3
ASSESSMENT DETAILS 6
1. APPLICANT AND NOTIFICATION DETAILS 6
2. IDENTITY OF CHEMICAL 6
3. COMPOSITION 6
4. PHYSICAL AND CHEMICAL PROPERTIES 7
5. INTRODUCTION AND USE INFORMATION 7
6. HUMAN HEALTH IMPLICATIONS 9
6.1. Exposure Assessment 9
6.1.1. Occupational Exposure 9
6.1.2. Public Exposure 10
6.2. Human Health Effects Assessment 10
6.3. Human Health Risk Characterisation 13
6.3.1. Occupational Health and Safety 13
6.3.2. Public Health 14
7. ENVIRONMENTAL IMPLICATIONS 14
7.1. Environmental Exposure & Fate Assessment 14
7.1.1. Environmental Exposure 14
7.1.2. Environmental Fate 16
7.1.3. Predicted Environmental Concentration (PEC) 16
7.2. Environmental Effects Assessment 18
7.2.1. Predicted No-Effect Concentration 18
7.3. Environmental Risk Assessment 19
APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES 20
Appendix B: Toxicological Investigations 21
B.2. Developmental toxicity 21
APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS 22
C.1. Ecotoxicological Investigations 22
C.2.1. Inhibition of microbial activity 22
BIBLIOGRAPHY 23

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/1544	Solvay Chemicals Pty Ltd	Pentanoic acid, 5-(dimethylamino)-2-methyl-5-oxo-, methyl ester (Rhodiasolv PolarClean)	Yes	≤ 200 tonne/s per annum	Solvent in coatings, cleaning products and oil/gas drilling

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 for the 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*
Serious eye damage / eye irritation (Category 2A)	H319 - Causes serious eye irritation

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:

R36: Irritating to eyes

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and 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:
  - Serious eye damage / eye irritation (Category 2A) - H319 - Causes serious eye irritation

- The following should be used for products/mixtures containing the notified chemical:
  Conc. ≥ 10%: H319

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical as introduced and in products:
  - Local exhaust ventilation if possible (LEV)
  - Good general ventilation if LEV is not available
  - Closed processes if possible
  - Splash guards where appropriate

- 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 and in products:
  - Avoid eye contact
  - Avoid generation of aerosols
  - Avoid inhalation exposure
  - Clean up spills and splashes promptly

- 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 product:
  - Eye protection such as chemical goggles, face shields or safety glasses
  - Protective coveralls
  - Impermeable gloves
  - Respiratory protection if inhalation exposure may occur

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012a) or relevant State or Territory Code of Practice.

- 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.

Public Health

- The following measures should be taken by formulators and marketers of consumer cleaning products to minimise public exposure to the notified chemical:
  - Consider the irritation potential of the notified chemical as formulated into consumer cleaning products.

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.

Storage

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

Emergency procedures

- Spills and/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 concentration of the notified chemical is proposed to exceed 20% in consumer products;
- additional information becomes available on the aspiration hazard of the notified chemical.

and

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical is likely to change from solvent in coatings, cleaning products and oil/gas drilling;
- 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.

(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

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Solvay Chemicals Pty Ltd (ABN: 80 004 449 870)
44 Real Avenue
Norman Park QLD 4170

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Foreign scheme.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: other names, analytical data, purity, identity and level of impurities, use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: acute inhalation toxicity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada, USA, EU, New Zealand, Switzerland

2. IDENTITY OF CHEMICAL

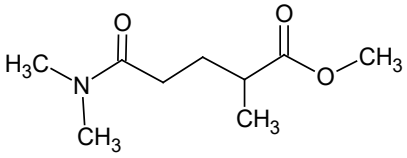
MARKETING NAME(S)
Rhodiasolv PolarClean

CAS NUMBER
1174627-68-9

CHEMICAL NAME
Pentanoic acid, 5-(dimethylamino)-2-methyl-5-oxo-, methyl ester

MOLECULAR FORMULA
$C_9H_{17}NO_3$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
187.24 g/mol

ANALYTICAL DATA
Reference NMR, FTIR, GC and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 70%

IMPURITIES/RESIDUAL MONOMERS
Several impurities in the notified chemical have been identified.

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa:
Colourless to pale yellow liquid.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	<-60°C	OECD TG 102, ISO 1392
Boiling Point	280°C at 101.3 kPa	OECD TG 103, ISO 918
Density	1,043 kg/m^3 at 20°C	OECD TG 109, ISO 758
Vapour Pressure	<0.0001 hPa at 20 °C	OECD TG 104, ISO 918
Water Solubility	> 490 g/L at 24°C	Measured
Hydrolysis as a Function of pH	Hydrolytically stable at pH 4 and 7. At pH 9: $t_{1/2}$ = 342 h (25°C)	Measured
Partition Coefficient (n-octanol/water)	log Pow = 0.39 at 20 °C	Measured
Adsorption/Desorption	log K_{oc} = <1.25 at 30°C	Measured
Dissociation Constant	Not determined	No dissociable functionality.
Flash Point*	144-146°C at 101 kPa	EC Regulation Nº440/2008, ISO 2719
Flammability in air	Not determined	Not expected to readily form flammable atmospheres because of low volatility.
Autoignition Temperature*	390°C	EC Regulation Nº440/2008-A15 and NF T20-037
Explosive Properties*	Not explosive	Not expected to have explosive properties based on the lack of structural alerts. This was also confirmed by studies according to EC Regulation Nº440/2008-A14 and NF T20-038.
Oxidising Properties	Not determined	Not expected to have oxidising properties based on the lack of structural alerts.
Surface tension	69 mN/m (23°C)	ISO 304
Viscosity*	Kinematic viscosity 9.40 ± 0.02 mm^2/s at 23 °C Dynamic viscosity 9.78±0.06 mPa.s at 23 °C	ISO 3104; OECD TG 114

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

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

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System 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 may be imported in a finished product or it may be imported as a neat raw material for local use or reformulation into end use products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	50-200	50-200	50-200	50-200	50-200

PORT OF ENTRY
Sydney, Melbourne, Adelaide, Brisbane and Perth

IDENTITY OF MANUFACTURER/RECIPIENTS
The notifier.

TRANSPORTATION AND PACKAGING

The notified chemical may be imported in neat form in bulk, 205 L drums or 1000 L IBC and used for local reformulation into end-use products. It may be imported as a component of finished end-use products. The size and type of containers for end-use products will vary depending on application type: 500 ml trigger spray for cleaning products, 20 L cans for coatings and 205 L drums and 1000 L IBC for industrial and oilfield applications.

USE
The notified chemical will be used as a polar solvent. The application areas will be in:
- Coatings (containing 0.5% - 5% notified chemical),
- Oil/gas field applications (containing 5%-10% notified chemical);
- Industrial cleaning products (containing 95% -100% notified chemical) and
- Domestic cleaning products (containing 5-20% notified chemical).

OPERATION DESCRIPTION
Reformulation
The notified chemical will be reformulated into end use products using automated liquid blending and filling operations under local exhaust ventilation. During reformulation, the neat chemical will be transferred from the import containers to closed stainless steel blending tanks, by removing the bungs and connecting hoses and pumping equipment. High speed dispersion and mixing will be used to blend the notified chemical with other components. Quantities of the final formulations containing the notified chemical will be sampled and tested by QA Personnel for quality control purposes before packaging for end-use. The finished product is filled in various containers using automated guarded filling equipment under ventilation extraction system.

Coatings

The coatings containing the notified chemical at up to 5% are expected to be applied by painters to various substrates by airless spraying, rollers or brush. The measuring, mixing and pouring the mixture into a spray gun are expected to be in an open system. Collected overspray is expected to be disposed of by licensed waste contractors. The spray equipment, brushes and rollers are expected to be cleaned manually using water, newspapers and rags followed by rinsing with water or recycled paint solvent depending on the equipment, and the washings disposed of by solvent recyclers or (in the case of water) disposal to sewer.

Consumers may also apply coatings using brushes, rollers or spray in DIY applications.

Oilfield use

The formulated products containing up to 10% of the notified chemical will be used in offshore and onshore oil and gas operations. The products will be transferred from drums or IBCs to containers using hoses and pumps followed by transferring to an on-site holding tank. The formulation is expected to be injected downwell from the holding tank and the fluid pumped back out and stored in pits on the rig after the injection. The recovered water phase may be re-injected into the reservoir for pressure maintenance or it will be further diluted and then discharged into the ocean in batch mode. When used for on-shore operations, the retrieved fluid will be collected and sent to on-site treatment and water recycling process.

Cleaning products

Industrial cleaning products containing the notified chemical at concentrations of up to 100% could be used for the cleaning of tools (e.g. rollers, brushes, spray gun, injection heads). The products can also be used for manual

cleaning. The products are expected to be used by either flushing of equipment with the product (for large equipment) or spraying it onto surfaces or cloths followed by wiping the surfaces with a rag.

Consumers may use domestic cleaning products (containing up to 20% notified chemical) supplied in trigger spray packages.

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	1-8	20
Formulation/Repackaging		
Blending/filling	2-4	5-10
QA	0.5	5-10
Coatings		
Professional painters	2-4	100-200
Oilfield		
Oil and gas rig workers	2-4	20-40
Industrial Cleaning		
Factory workers	3-8	260

EXPOSURE DETAILS

Transport and storage

During transport and storage, exposure of workers to the notified chemical at up to 100% will only occur in the unlikely event of an accidental release.

Reformulation

Dermal, ocular, inhalation and ingestion exposure to the notified chemical at up to 100 % concentration may occur during reformulation processes [e.g., inhalation exposure during transfer of the notified chemical if vapour or mist is generated, dermal and/or ocular exposure during quality control processes and cleaning equipment if drips and spills occur]. However, exposure is expected to be limited by the use of local exhaust ventilation, splash guards, PPE such as respirator, full-face shield, solvent resistant gloves, and goggles as well as industrial protective clothing.

The reformulation process is expected to be similar for the manufacture of coatings, cleaning or oilfield products leading to similar exposure to the notified chemical during the processes.

Coatings

There is potential for dermal and ocular exposure to the coatings containing up to 5% of the notified chemical during application and clean-up processes, as well as inhalation exposure during spray application. Standard clean-up process is likely to involve both workers and licensed waste contractors. Worker exposure is expected to be limited by the stated use of respiratory protection, chemical goggles or face shield, protective overalls, safety boots and impermeable gloves.

Oil/gas applications

Workers involved in the oilfield operations will have potential for dermal, ocular and inhalation exposure to the notified chemical at up to 10%. Exposure during transfer operations is expected to be minimised by the use of quick connect fittings and use of personal protective equipment (gloves, goggles and overalls). Inhalation exposure is not expected to be significant unless aerosols are generated, as the notified chemical has a low vapour pressure. In addition the products are expected to be used in an open area, reducing the potential for build-up of any vapours or mists.

Industrial cleaning

Dermal, ocular, and inhalation exposure of workers to the notified chemical (concentrations up to 100%) are potentially high due to the nature of the manual handling of products containing high concentrations of the notified chemical. Aerosols may be generated, especially during spray cleaning. This could result in secondary exposure as ingested droplets as a result of inhaling them. Exposure is expected to be lowered by the use of personal protective equipment that is likely to include anti-static overalls and footwear, respirators, full-face shield, goggles and gloves. The notifier states that work places are expected to have good ventilation.

6.1.2. Public Exposure

Public exposure is expected to occur when the notified chemical is used in DIY coating products at up to 5% and in domestic cleaning products at up to 20%.

Coatings may be applied by consumers using brush, roller or spray. The notifier stated in the application that the public are less likely to use spray as the method of application. It is not known whether protective equipment would be used by consumers during paint application. Consumers would be expected to avoid paint splashes, and wash any spills from the skin. Once dried, much of the notified chemical would remain trapped in the paint matrix and consumer exposure is not expected.

When domestic cleaning products are applied, inhalation, dermal or ocular exposure of consumers may occur. The highest potential for inhalation will occur during use of sprays. This exposure is expected to be minimised by using the spray container at a close distance from the surface to be cleaned. It is also expected that the aerosol droplets will be relatively coarse and will settle out of the air rapidly. Consumers may or may not wear gloves that would reduce dermal exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on commercial forms of the notified chemical (>70% purity) are summarised in the following table. For full details of the asterisked study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 >2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	Not determined
Rabbit, skin irritation	Non-irritating
Eye irritation (The Bovine Corneal Opacity and Permeability Assay)	Non-corrosive
Rabbit, eye irritation	Irritating
Mouse, skin sensitisation – Local lymph node assay	No evidence of sensitisation
Rat, repeat dose, oral toxicity – 28 days.	NOAEL= 1000 mg/kg/day
Repeated dose toxicity (90 days)	NOAEL= 1000 mg/kg/day
Mutagenicity – Bacterial Reverse Mutation	Non mutagenic
Mutagenicity – Induction of point mutations	Non mutagenic
Genotoxicity- in vitro-Chromosome Aberration	Non genotoxic
Genotoxicity- in vivo -Mouse micronucleus assay	Non genotoxic
Rat, reproductive and developmental toxicity (combined with repeated dose), oral	NOAEL= 1000 mg/kg/day
Pre-Natal Developmental toxicity*	NOEL= 1000 mg/kg/day

Toxicokinetics, metabolism and distribution

No specific toxicokinetic studies are available on the notified chemical. Based on the partition co-efficient (log Kow = 0.39) and the low molecular weight (<500 Da), dermal absorption may occur. The notified chemical may also be absorbed across the respiratory and GI tracts.

Acute toxicity

The notified chemical was of low acute oral toxicity in a study conducted in rats to the OECD 423 test guidelines (LD50>2000 mg/kg bw). Briefly, two groups, each of three female CRL: (W1) BR Wistar rats, were treated with the notified chemical by gavage at a dosage of 2000 mg/kg bw. The test item was administered undiluted at a dosing volume of 1.92 mL/kg . All animals survived until the end of the study period. No clinical signs were observed during the course of the study. The body weight of the animals was within the range commonly

recorded for this strain and age. No macroscopic findings were recorded at necropsy. Based on the results of this study, the notified chemical is expected to be of low acute oral toxicity.

Acute dermal toxicity of the notified chemical was tested on male and female Wistar rats (5/sex). Animals received a single application of 2000 mg/kg to the shorn skin under a semi-occlusive dressing for 24 hours. No deaths occurred and no systemic or local signs of toxicity were observed. Clinical signs included red/brown staining around the snout of two males during the day of dosing. The acute dermal median lethal dose (LD50) of the test item was found to be >2000 mg/kg body weight. Based on the results of this study, the substance may be classified as having low acute dermal toxicity.

No acute inhalation data were provided. The vapour pressure is relatively low, indicating exposure to vapour is unlikely, at ambient temperature. However, the notified chemical has a kinematic viscosity of 9.40 ± 0.02 mm2/s at 23 °C. Substances that have a kinematic viscosity of 14 mm2/s or less, measured at 40º C, on the basis of existing animal studies and expert judgement that also takes into account surface tension, water solubility, boiling point, and volatility, cause concern owing to the presumption that they cause human aspiration toxicity hazard, according to the GHS (2009). As not all of this information is available for the notified chemical, there is uncertainty about its potential aspiration hazard.

Irritation and sensitisation

Skin irritation

A primary skin irritation study was conducted with the commercial form of the notified chemical on NZW rabbits. The substance (0.5 mL) was applied to the shorn skin in a single 4-hour occluded application. No deaths occurred and no clinical signs of systemic toxicity were observed. The test item did not elicit any skin reactions (PII=0). The notified substance is not considered to be a dermal irritant under the conditions of this study.

Acute eye Irritation

A primary eye irritation study was conducted with the commercial form of the notified chemical on three NZW rabbits. 0.1 mL of the substance was placed into the lower conjunctival sac of one eye while the other eye served as control. No deaths occurred and no evidence of systemic toxicity was observed. Initial pain reaction was noted in all animals (score 2). One hour after application, conjunctival redness, chemosis, and discharge were noted in all animals and corneal opacity was noted in 2 animals. One week after treatment, conjunctival redness was noted in two animals and corneal opacity was noted in one animal. No clinical signs were noted after 14 days (MMS=30.5). The notified substance is considered to be a moderate eye irritant under the conditions of this study.

The notified chemical was found to be not corrosive to the eyes in a Bovine Corneal Opacity assay.

Skin sensitisation (LLNA)

The potential for the commercial form of the notified chemical to induce skin sensitisation was determined using the local lymph node assay. The main test was performed in twenty CBA/J@Rj mice (4 animals/groups). For three consecutive days, the test substance (25 µL /ear) prepared in acetone: olive oil (AOO, 4:1, v/v) was applied to the dorsal surface of both ears of the study animals, at a concentration of 10%, 25%, or 50%. None of the animals died during the course of the study and no signs of systemic toxicity were noted. Stimulation index values of the test item were 1.2, 1.6 and 1.7 at treatment concentrations of 50%, 25% and 10%, respectively. The notified substance is not considered a skin sensitiser under the conditions of this assay.

Repeated dose toxicity

Two sub-chronic toxicity studies were conducted on the commercial form of the notified chemical.

Repeated dose oral toxicity test (90days):

A 90-day oral repeated dose toxicity study was conducted on Wistar rats. The animals received the substance by oral gavage at a dose of 100, 300, or 1000 mg/kg daily for 90 days.

No unscheduled deaths were noted. Clinical signs included hunched posture, hypoactivity, piloerection, dyspnea, loud breathing, ptyalism, and opacity.

Functional observation battery: Abnormal fur appearance was noted in all animals at all doses, abnormal posture was noted in mid and high dose males.

Blood biochemistry: Statistically significant differences were noted for chloride (decrease in males), protein (decrease in females), albumin (decrease in females), and alanine aminotransferase (increase in males). In the absence of dose-relationship and/or similar findings in the opposite sex, a test item treatment-related effect was considered unlikely.

Organ weights: An increase in absolute and relative kidney weight was noted in high dose females. Increased kidney weights in high-dose females were without correlating microscopic findings, and were therefore considered to be of no toxicological significance.
Microscopic changes: The small increase in incidence and severity of hyaline droplets in the tubular epithelium of high-dose males was considered to be incidental as a similar finding was observed in control animals.
No significant changes were noted for motor activity, body weight, ophthalmology, and hematology. No macroscopic findings were noted at terminal necropsy.
In the absence of significant adverse findings at the highest dose level tested, a NOAEL of 1000 mg/kg/day was established. This is indicative of low repeated-dose oral toxicity.

Combined repeated-dose toxicity with reproductive/developmental screen (28 days):
A combined 28 day oral repeated dose with screening reproductive and developmental toxicity study was conducted on Wistar rats. The animals received the substance by gavage at a dose of 30, 300, or 1000 mg/kg daily. Duration of exposure was 42 days (14 days pre-pairing, pairing, gestation, and early lactation).
No unscheduled deaths were noted. Clinical signs included transient episodes of increased salivation seen soon after dosing and again on days 30 - 45.
Hematology: Statistically significant findings were confined to males of the mid and high dose groups that showed a slight reduction for mean corpuscular haemoglobin concentration. A reduction in activated partial thromboplastin time was also noted for high dose males.
Blood chemistry: No toxicologically significant findings were noted. Mid and high dose males showed increases for plasma bile acid levels. High dose males also showed an increase in plasma creatinine concentration. However, with no correlating histopathology, these findings were considered to be incidental.
Organ weights: High dose males showed an increase in liver weight both absolute and relative to body weight. High dose females showed an increase in absolute and relative kidney weight. These findings were mostly within historical ranges and were not considered biologically relevant given the lack of histopathology findings. Low dose females showed increased absolute and relative heart weight and decreased absolute and relative thyroid weight. However, in the absence of a dose-dependent relationship, these findings were not considered to be relevant.
Histopathology: Minimal to slight centrilobular hepatocyte hypertrophy was noted in 4/5 high dose males. These changes were not noted in high dose females or mid or low dose animals. These findings are considered to be adaptive in nature.
Offspring growth and development: No significant differences were noted for litter weights or mean offspring body weight. No obvious clinical signs of toxicity were detected from offspring of treated females. Incidental clinical signs detected throughout all groups (including control) included small size, offspring found dead or missing, bruising, no milk in stomach, and cold and physical injuries. These were considered unrelated to test item toxicity.
No significant changes were noted for the following parameters: functional observation battery, body weight, food consumption, water consumption, mating, fertility, gestation length, and offspring litter size and viability. No macroscopic abnormalities were detected at terminal necropsy.
Since no toxicologically significant effects were noted at the highest dose, the NOAEL is considered to be 1000 mg/kg/day. No treatment related effects were noted for reproduction and development, therefore a NOAEL of 1000 mg/kg/day was established.These values are indicative of low oral repeated dose and are also suggestive of low reproductive and developmental toxicity of the notified chemical.

Mutagenicity/Genotoxicity
Bacterial reverse mutation assay
The commercial form of the notified chemical was evaluated for *in vitro* mutagenicity in a bacterial reverse mutation assay at concentrations of 33-5000 µg/plate, in both the presence and absence of metabolic activation (S9). Neither an increase in the number of revertant colonies nor a dose-related response was observed in four strains of *S. typhimurium* (TA98, TA100, TA1535, and TA1537) either with or without metabolic activation. The substance is considered negative for *in vitro* mutagenicity under the conditions of this assay.

Chromosomal aberrations assay
The notified chemical was also tested for *in vitro* clastogenicity in a chromosomal aberrations assay using human peripheral lymphocytes. In the first assay, cells were exposed to the substance for 4 hours, at a concentration range of 14.4- 2220 µg/mL, both in the presence and absence of metabolic activation (S9). In the second assay, cells were exposed to the substance at a concentration range of 236.7- 2220 µg/mL for 4 hours +S9, or 22 hours –S9. In both experiments, no biologically or statistically significant increase in the number of cells carrying structural chromosome aberrations was observed. The notified substance is considered negative for *in vitro* clastogenicity under the conditions of this assay.

Mammalian cell gene mutation (V79/HPRT)
The notified chemical was evaluated for *in vitro* mutagenicity in a mammalian cell gene mutation assay using Chinese hamster lung fibroblast (V79/HPRT) cells. In the first assay, cells were exposed to the substance for 4 hours (concentration range; 69.4 - 2220 µg/mL) with or without metabolic activation (S9). In the second assay, cells were exposed to the substance (concentration range; 138.8- 2220 µg/mL) for 4 hours +S9, or 24 hours –S9. No relevant and reproducible increase in the mutant frequency was observed in Exp 1. A linear regression analysis identified a significant dose dependent trend of the mutation frequency in Exp 2 with S9. However, the mutation frequency remained within historical control ranges and was considered irrelevant. The notified substance is considered negative for *in vitro* mutagenicity under the conditions of this assay.

Mouse micronucleus assay
The notified chemical was also tested for *in vivo* clastogenicity in a mouse micronucleus assay. Cd-1 mice.
Seven male mice/group received the substance by intra-peritoneal injection at a dose of 500, 1000 or 2000 mg/kg. Hunched posture, ptosis, and ataxia were noted in animals of the mid and high dose groups. Laboured breathing, decreased respiratory rate, and loss of righting reflex were noted in high dose animals. There were no statistically significant or biologically relevant increases in the frequency of the detected micronuclei at any preparation interval and dose after administration. The substance is considered negative for *in vivo* clastogenicity under the conditions of this assay.

Reproductive and Developmental toxicity
No significant effects on reproduction or development were seen in a prenatal developmental toxicity study to OECD TG41. Isolated recordings of foetal skeletal malformations were considered by the study authors not to be treatment related. The NOEL was set at the highest dose tested of 1000 mg/kg bw/day.

Impurities
Although not considered in this risk assessment, NICNAS notes that the notified chemical contains an impurity that is classified as hazardous according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The impurity is not present in the notified chemical above the cut off concentration for classification.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System for the 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*
Serious eye damage / eye irritation (Category 2A)	H319 - Causes serious eye irritation

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):
R36: Irritating to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available toxicological data, the notified chemical is expected to exhibit a relatively low toxicity profile, except for eye irritancy. It may also be irritant to the nose, throat and respiratory system if inhaled, and to the GI tract if ingested, based on predicted alerts associated with substructures of the notified chemical and as stated in the SDS. It is noted that repeated dose toxicity information is available only for the oral route.

The range of proposed uses, varying concentrations and the different potential routes of exposure mean that workers carrying out different tasks may have quite different levels of exposure and risk. A scenario with a likely high potential exposure is industrial cleaning, as the chemical will be used at a high concentration up to 100%, and there may be manual processes and few engineering controls. Spray application or generation of mists/aerosols would increase the potential for inhalation exposure in this and other scenarios, as would use at elevated temperatures where vaporisation may occur. Some sites of use are not expected to have local exhaust

ventilation, and would rely on good general ventilation to reduce any inhalation exposure. Appropriate workplace measures, using the hierarchy of controls, would reduce worker exposure and the risk of irritation effects. These would include isolation and engineering controls, safe work practices and PPE.

If such workplace controls are in place, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The notified chemical is classified as an eye irritant, and may also be irritant to the nose, throat and respiratory system if inhaled, and to the GI tract if ingested.

The potential for direct dermal, ocular and inhalation exposure of the public to the notified chemical at up to 5% is expected when coatings (DIY use) are applied by using brush, roller or spray. It is not known whether any PPE would be used by consumers during paint application. The frequency and extent of exposure is expected to be less than that of professional painters. Irritant effects are expected to be lessened by the relatively low concentration of use. Once the paint has dried, significant exposure to the public is not expected.

Dermal, inhalation and ocular exposure is possible when products containing the notified chemical (up to 20%) are used for domestic cleaning by trigger spray application. The potential for ocular and inhalation exposure and irritation may be increased because of the spray method of application.

Under the proposed uses, the risk to the public from use of the notified chemical is not considered unreasonable. However, formulators should address the irritancy potential of the notified chemical when formulating consumer products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical is not manufactured in Australia; therefore, release to the environment is not expected due to manufacturing activities. Releases to the environment may occur following accidental spills during import, transport or storage. Notified chemical that is spilled is expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations.

The notified chemical may either be imported in ready-to-use products or in products for further reformulation in Australia. The concentration of the notified chemical in end-use products will vary greatly (5% to 100%) depending on the type of product, as it will be used as a solvent.

At the reformulation/repackaging sites the notified chemical will be blended and filled into end-use containers using automated processes. These operations will be conducted in bunded areas. Any spilled material will be collected using a suitable absorbent material and placed in 205 L drums for disposal to landfill. Residues on surfaces will be washed with water to sewer.

Once mixing is complete the reformulated product is automatically pumped to filling machines for packaging into containers. Empty containers, mixing vessels and transfer lines are cleaned with water and recycled where possible. Waste generated during the blending process is expected to be less than 0.5% of import volume, resulting from residues in import containers (0.25% of import volume) and spills and leaks (0.25% of import volume). Empty drums will be sent to a drum recycler for reclamation.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be used in surface coatings, oilfield, industrial, and domestic cleaning products.

Coatings

Prior to application to surfaces, the coatings will be mixed with other components until the desired viscosity is achieved. The majority of the coatings will be applied using spray application techniques with small areas applied using brushes or rollers. Losses through spray application include overspray (generally 15-20%) and equipment cleaning (1-2%). Application using brushes and rollers results in releases from dripping (<1%) and equipment cleaning (5%). Overspray will be collected through the use of protective curtains and floor sheeting. Collected overspray will be disposed of by licensed waste contractors. Residual paint mixture is likely to be washed from the equipment manually using water or recycled paint solvent, and the washings disposed of by solvent recyclers or in the case of water disposal will be to sewer. Similarly, brushes and rollers will be cleaned using newspaper or rags followed by rinsing with water and the washings will be disposed of to sewer.

Oilfield use

The notified chemical may be used in both off-shore (60%) and on-shore (40%) oil and gas operations. The notified chemical is likely to be used within the common oilfield areas such as the northwest shelf of Western Australia and Bass Strait. Release during use in oilfields may results from accidental spills or leaks and from residues in empty containers. The notified chemical will be used in wells (total of 50 wells) at a concentration of up to 10%. When the well treatment has been completed, the fluid mixed with other aqueous content of the well will be pumped back out and stored in pits on the rig. The notified chemical is estimated to be diluted 10-fold in the pit. The recovered water phase may be re-injected into the reservoir for pressure maintenance or it will be further diluted and then discharged into the ocean in batch mode. When used for on-shore operations, the retrieved fluid will be collected and sent to on-site treatment and water recycling process. The amount of the notified chemical discharged to seawater in a batch process can be calculated as:

The volume expected to be used in oilfield applications = 200 tonnes/year
Amount used per well (Assuming 50 wells/year – exploration and development wells) = 4 tonnes/year/well
Assuming 50% will be re-injected and 50% collected for batch discharge, the total of batch discharge per year (4 × 50%) = 2 tonnes/year/well

Industrial Cleaning

When manual cleaning is used, the notified chemical will be absorbed onto rags which will be either disposed of to landfill or will be incinerated. When the notified chemical is used for flushing out equipment, it will be re-used as far as practical. When the solvent can no longer be re-used, it will be collected and disposed of to a liquid waste facility by licensed waste contractor. At the waste facility the solvent may be reclaimed by distillation or it may be mixed with other water-soluble waste streams and disposed of to sewer via their on-site waste treatment plant.

Domestic Cleaning

Residues in empty containers will be disposed of to landfill. When cleaning is conducted with rags, the notified chemical will be adsorbed onto the rag which will be disposed of to landfill. When the surface is cleaned with a sponge, the sponge may be washed under a tap and reused. In this case, the notified chemical will be released to sewer.

RELEASE OF CHEMICAL FROM DISPOSAL

Reformulation/Repackaging sites

During these operations waste generated are expected to be less than 0.5% of the import volume, resulting from residues in import containers (0.25% of import volume). These will be disposed of to sewer. Spills and leaks (0.25% of import volume) will be adsorbed onto inert material and disposed of to landfill.

Coatings

Dried coatings applied to surfaces will have the same fate as the substrate and it is likely to end up in landfill at the end of its lifecycle. Coatings residue in empty containers will be disposed of to landfill. Washings will be released to sewer.

Oilfield use

During use some chemical will be left as residues in empty containers. These containers will be returned back to shore and will be sent to recyclers where the containers will be washed. The washings will be diluted and sent to an on-site treatment plant followed by release to sewer. Releases during normal product transfer operations will be collected and discharged to ocean or surface water via large holding ponds for evaporation.

Industrial Cleaning

It is expected that emptied import drums containing residual chemical will be used to collect liquid waste and when full will be collected by a licensed hazardous waste contractor. The liquid contents will be treated and disposed of and the drums will be disposed of to a licensed waste landfill. The majority of the notified chemical will be disposed of through the sewer as a result of its use as an industrial cleaner.

Domestic cleaning

Disposal will be to landfill (residues in empty containers and cleaning rags) or sewer (washing cleaning sponges).

7.1.2. Environmental Fate

The notified chemical is a high boiling point (278-282°C) polar solvent (log Pow = 0.39) with low vapour pressure (<0.0001 hPa at 20 °C). Therefore, it is expected to have low partitioning to the atmosphere.

The majority of the notified chemical used for coatings is expected to adhere to the surface to which it is applied. Treated articles and other dried residues containing the notified chemical are expected to ultimately be disposed of to landfill. When associated with the article to which the product containing the notified chemical has been applied, the notified chemical is not likely to be mobile or bioavailable in landfill.

The notified chemical has a low adsorption/desorption coefficient (log Koc ≤ 1.25) which indicates that it will have low likelihood of partitioning to sediments, organic matter in soil or sludge in the sewer system. The water soluble notified chemical is not expected to bioaccumulate based on the low estimated water-octanol partition coefficients of 0.39. The notified chemical is hydrolytically stable at pH 4 and 7, but is expected to undergo slow abiotic hydrolysis under alkaline conditions. The notified chemical does not meet the criteria for ready biodegradability (33.7% biodegradation over 28 days), but it is inherently biodegradable (95.8 % biodegradation over 28 days). The calculated bioaccumulation factor is low (log BCF = 0.5). Therefore, the notified chemical is not expected to be persistent or bioaccumulative in the environment.

During oilfield operations, the notified chemical will be used as a mutual solvent for increasing oil/water compatibility in water-based drilling fluids used during stimulation and workover operations. It will be used in the drilling activities until target depth has been achieved. It will not be used during production phases. The frequency of batch release will depend on the particular well and is likely to be either daily or weekly. However, the test results for biodegradability studies in seawater have not been provided by the notifier.

The water soluble notified chemical is not expected to adsorb strongly to solids. Hence, the notified chemical discharged into seawater in the vicinity of off-shore oil- and gas-production sites is expected to be dispersed by tidal and ocean currents. The notified chemical is expected to remain dissolved in seawater until degraded by abiotic processes.

7.1.3. Predicted Environmental Concentration (PEC)

The intended volume for each use of notified chemical is exempt from publication. Therefore, the risk assessment assumes a worst case scenario where the total import volume of 200 tonnes and 100% release to the environment is used for the Predicted Environmental Concentration (PEC) analysis for each use. The combined maximum annual release of the notified chemical due to coatings, oilfield and cleaning activities are detailed in the table below.

Coatings, industrial and domestic cleaning

Predicted Environmental Concentration from coatings and industrial cleaning

The PEC for coatings and industrial cleaning was calculated using a conservative scenario where the total annual import volume is released to sewer over 200 working days per year across the nation.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	200,000	kg/year
Proportion expected to be released to sewer	100%	

Annual quantity of chemical released to sewer	200,000	kg/year
Days per year where release occurs	200	days/year
Daily chemical release:	1000.00	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	221.11	µg/L
PEC - Ocean:	22.11	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 221.115 µg/L may potentially result in a soil concentration of approximately 1.474 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 7.370 mg/kg and 14.74 mg/kg, respectively.

Predicted Environmental Concentration from domestic cleaning

The PEC calculation for domestic cleaning is summarised in the table below. Based on the reported use in domestic cleaning detergents, it is assumed that 100% of the total volume of the notified chemical is released to sewer on a nationwide basis over 365 days per year.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	200,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	200,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	547.95	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	121.16	µg/L
PEC - Ocean:	12.12	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 121.159 µg/L may potentially result in a soil concentration of approximately 0.81 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 4.039 mg/kg and 8.077 mg/kg, respectively.

Based on the above calculations the combined PEC for the aquatic compartments are calculated as follows:

Predicted Environmental Concentration (PEC) for release to the aquatic compartment during use		
PEC – River (221.11 + 121.16)	342.27	µg/L
PEC – Ocean (22.11 + 12.12)	34.23	µg/L

Oilfield

The highest concentrations of drilling chemicals from water-based muds that occur in the vicinity of off-shore oil and gas production facilities arise from the batch-wise discharge of drilling muds (Thatcher et al., 2005). These discharges occur when drilling muds need to be diluted, when drilling of a section has been completed and the mud is to be changed, or when drilling at a particular well is complete and the rig is to be moved to a new location. The rate of discharge of muds in the batch-wise disposal method is much larger than the continuous discharges of mud entrained in drill cuttings produced during drilling operations (Thatcher et al., 2005). Hence, the batch-wise disposal method for used drilling mud has the potential to generate higher peak concentrations of the notified chemicals in seawater in the vicinity of off-shore drilling sites than the continuous discharge of drilling muds entrained in cuttings.

In the CHARM model (Thatcher et al., 2005, p. 23), the PEC for drilling chemicals in seawater resulting from batch-wise discharge of water-based muds ($PEC_{water,batch}$/ mg L^{-1}) is calculated using the following equation:

$$PEC_{water,batch} = \frac{M}{V_m} \times D_{batch} \times 10^3$$

In this relationship, $PEC_{water,batch}$ is related to the amount of chemicals discharged (M/ kg), the volume of mud discharged for the specific section drilled (V_m/ m^3), and the dilution factor for batch-wise discharges (D_{batch}/ unitless). The specific values for volume of mud discharged and the dilution factor have not been provided for operations under Australian conditions. Hence, the default values for V_m (375 m^3 for a 1500 m drill length) and D_{batch} (7.7×10^{-5}) as specified in the CHARM model for the batch-wise discharge scenario have been used for this calculation (Thatcher et al., 2005, p. 46). Based on these default values, and the worst case discharge of 2000 kg of notified chemical in a single batch of used mud, the $PEC_{water,batch}$ for the notified chemical is calculated to be 0.411 mg/L ($PEC_{water,batch} = 2000 \div 375 \times 7.7 \times 10^{-5} \times 10^3$).

The $PEC_{water,batch}$ calculated above is based on a theoretical worst-case in which all of the mass of notified chemical discharged with a batch of mud is present in seawater within a radius of 500 m from the discharge point. The concentration of the notified chemical in sediment ($PEC_{sediment}$) is not significant due to its high solubility.

7.2. Environmental Effects Assessment

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

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

Based on the endpoints for toxicity of the notified chemical to aquatic organisms, the notified chemical is not considered to be harmful to aquatic organisms under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Therefore, the notified chemical is not formally classified under the GHS. Based on its measured acute toxicity, biodegradability and expected low bioaccumulation potential, the notified chemical is not formally classified under the GHS for the chronic hazard.

The notified chemical is expected to be used in offshore oil and gas operations. However, ecotoxicity studies and data for marine (saltwater) fish, marine aquatic invertebrates and marine algae have not been provided.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) for the notified chemical has been calculated and is presented in the table below. The PNEC was calculated based on the endpoints for test species and an assessment factor of 100. The conservative assessment factor of 100 was used since measured ecotoxicological data for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga)	> 100	mg/L
Assessment Factor	100	
PNEC:	> 1,000	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotients (Q = PEC/PNEC) have been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Coatings, industrial and domestic cleaning			
Q - River:	342.27	> 1,000	< 0.342
Q - Ocean:	34.23	> 1,000	< 0.034
Oilfield			
Q - Ocean:	410.67	> 1,000	< 0.411

The Risk Quotients (Q = PEC/PNEC) for the notified chemical in coatings, oilfield, industrial and domestic cleaning products have been calculated to be < 1 for the river and ocean compartments. Therefore, the notified chemical is unlikely to result in ecotoxicologically significant concentrations in the aquatic environment from the assessed use pattern.

The notified chemical is inherently biodegradable, thus it is unlikely to persist in surface waters or soils. The notified chemical is considered to have low potential for bioaccumulation. Therefore, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment from the assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Flash Point 146 °C at 1000hPa

Method	EC Council Regulation No 440/2008 A.9 and EN 2719.
Remarks	The flash point was made according to a normalised, valid method depending of the range of temperatures. The assumed value was 150°C. The Pensky Martens Method was used for flash point measurement above 50 °C in closed cup in accordance with EN ISO 2719.
Test Facility	Rhodia Operations (2009)

Autoignition Temperature 390°C

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases) and NF T 20-037.
Remarks	The apparatus used is ISL VO7903 normalised, according to EC Council Regulation No 440/2008 A.15 and NF T 20-037. The method involves varying the temperature and the injected volume of material to obtain the minimum temperature at which an ignition occurs.
Test Facility	Rhodia Operations(2009)

Explosive Properties Negative

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	1. Thermal sensitivity test: The notified chemical has been determined not to have thermal sensitivity to explosion according to the thermal sensitivity test (Normalised"Koenen tube" according to Council Regulation CE 440/2008 and NF T20-038. 2. Shock test: The notified chemical has been determined not to have shock sensitivity to explosion. The apparatus used is a normalised BAM-fall hammer according to Council Regulation CE 440/2008 and NF T20-038.
Test Facility	Rhodia Operations(2009)

Viscosity Kinematic viscosity: 9.40 ± 0.02 mm^2/s at 23 °C
Dynamic viscosity: 9.78±0.06 mPa.s at 23 °C

Method	OECD TG 114 -Viscosity of Liquids.
Remarks	$\upsilon = \eta/\rho$, where υ= kinematic viscosity, η= dynamic viscosity and ρ= density of a fluid. The kinematic viscosity (υ) measured was 9.40 ± 0.02 mm^2/s at 23 °C. Therefore, the dynamic viscosity (η) is 9.78±0.06 mPa.s (where the interpolated density, ρ is 1.041 g/cm^3 at 23 °C).
Test Facility	Rhodia Operations(2009)

Appendix B: Toxicological Investigations

B.2. Developmental toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD 414 Prenatal developmental toxicity Study
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral –gavage
Exposure Information	Dosing from Day 6 to Day 20 *post-coitum*
Vehicle	Drinking water
Remarks - Method	No protocol deviation was made. The dose-levels were selected following the results of a previous study to OECD 422 where no toxicologically significant effects were observed up to 1000 mg/kg/day. Therefore, 1000 mg/kg/day was selected as the high dose-level for this study.

RESULTS

Group	*Number of Animals*	*Dose/Concentration mg/kg/day*	*Mortality*
I	24	0	No
II	24	100	No
III	24	300	No
IV	24	1000	No

Mortality and Time to Death

No mortality was observed during the treatment or recovery phases.

Effects on Dams

At termination on day 21 *post-coitum*, there were 23, 22, 21 and 21 dams with live foetuses in the vehicle control, 100, 300 and 1000 mg/kg/day groups, respectively. There were no test item related clinical signs, effects on mean body weights, mean body weight changes or mean food consumption. There were no test item related findings at necroscopy, and no effects on mean hysterectomy data (pre- and post-implantation losses, early and late resorptions).

Effects on Foetus

There were no effects of the treatment with the test item on mean foetal body weights or foetal sex ratios, no external variations or malformations, and no soft tissue malformations.

Foetal soft tissue variations: In the 300 mg/kg bw/day group, one foetus had a hemorrhagic eye. This variation was isolated and recorded in one foetus only.

Foetal skeletal cartilage: In the 1000 mg/kg bw/day group, 1/21 litter had a foetus with bipartite cartilage of thoracic vertebra. This finding was isolated and considered to be of no toxicological significance in the absence of associated variations or malformations.

Foetal skeletal malformations: At the high dose of 1000 mg/kg bw/day, two litters had a foetus with one absent lumbar vertebra, associated in both foetuses with a skeletal variation – presence of 25 pre-sacral vertebrae. This malformation was isolated and recorded in the Historical Control Data (two foetuses from 2/141 litters) and therefore considered by the study authors not to be related to the treatment with the test item.

Other effects on foetal skeletal cartilage and skeletal variations occurred across the groups and were not dose related.

Remarks - Results

It is noted that the fetal skeletal malformation occurred only at the highest dose, and was present in 2/21 litters in this group, however the incidence was not statistically significant. On the basis of all the results obtained in this study, the test authors considered there was no test-item related effect observed. Therefore, the NOEL for maternal parameters and for embryo-fetal development was considered to be 1000 mg/kg/day.

CONCLUSION

The NOEL was established as 1000 mg/kg bw/day under the conditions of the study.

TEST FACILITY CiToxLAB France (2013)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. 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: Control, 10, 32, 100, 320 and 1000 mg/L Actual: Not determined
Remarks – Method	Following a preliminary range-finding test, activated sludge was exposed to an aqueous dispersion of test substance at 21 ± 2 °C for 3 hours. The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.
RESULTS	
3h EC50	> 1000 mg/L
3h NOEC	> 1000 mg/L
Remarks – Results	It was considered unnecessary to test at concentrations in excess of 1000 mg/L. The reference item gave a 3-Hour EC_{50} value of 6.9 mg/L, 95% confidence limits 5.2 - 9.2 mg/L.
CONCLUSION	The notified chemical is not inhibitory to bacterial respiration
TEST FACILITY	Harlan Laboratories Ltd, UK (2011)

BIBLIOGRAPHY

CiToxLAB France (2013) Rhodiasolv Polarclean – Prenatal Developmental Toxicity Study by Oral Route (Gavage) in Rats, 24/1/13. CiToxLAB France, Evreux, France (Unpublished report submitted by the notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

SWA (2012a) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating.

SWA (2012b) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace.

Harlan (2011). Assessment of the Inhibitory Effect on the Respiration of Activated Sewage Sludge (Study No. 41100664, May 2011). Derbyshire, UK, Harlan Laboratories Ltd (Unpublished report submitted by the notifier).

Rhodia Operations (2009) [Notified Chemical] Main Physico-Chemical Properties. 9/10/09. Rhodia Operations, Aubervilliers Cedex, France. (Unpublished report submitted by the notifier).

Thatcher M, Robson M, Henriquez LR, Karman CC & Payne G (2005) Chemical Hazard Assessment and Risk Management (CHARM): A User Guide for the Evaluation of Chemicals Used and Discharged Offshore. CHARM Implementation Network, Version 1.4.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.