File No: SN/28

March 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine

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.

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
SN/28	Halliburton Australia Pty Ltd.	Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine	Yes	< 282 tonnes per annum	Additive for oil and 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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	*Hazard statement*
Skin sensitisation (Category 1)	H317-May cause an allergic skin reaction

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:

R43: May cause sensitization by skin contact

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 3	H402: Harmful to aquatic life
Chronic Category 3	H412: Harmful to aquatic life with long lasting effects

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

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

Environmental risk assessment
On the basis of the 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:
  - H317: May cause an allergic skin reaction

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

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation

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 in the product:
  - Enclosed, automated processes if possible
  - Ventilation system including local exhaust ventilation if possible

- 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 product:
  - Avoid skin and eye contact

- 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:
  - Impervious gloves
  - Protective clothing
  - Chemical goggles
  - Face shield (if splashing occurs)

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

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

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

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, 2012) or relevant State or Territory Code of Practice.

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 notified chemical is proposed to be used for hydraulic fracturing applications;

or

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

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

(Material) Safety Data Sheet
The (M)SDS of the 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(S)
Halliburton Australia Pty Ltd. (ABN: 73 009 000 775)
Level 17, 444 Queen Street
BRISBANE QLD 4000

Assessment of the notified chemical was carried out under the *Industrial Chemicals (Notification and Assessment) Act 1989* [the IC(NA) Act], as LTD/1640, with the Public Report of the assessment published in the *Chemical Gazette* of 7th October, 2014.

The Director of NICNAS was informed of significant change in the use of the notified chemical and also a significant increase in the introduction volume of the notified chemical in excess of the permitted volume under the limited category (1 tonne/annum). Under the IC(NA) Act, the Director declared that a secondary notification was required for the chemical known as Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine.

In accordance with section 65 of the *Industrial Chemical (Notification and Assessment) Act 1989* (the Act), notice requiring the secondary notification of Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine was published in the *Chemical Gazette*. The notice of 1st September, 2015 stipulated that the following data were required to undertake further assessment of Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine;

- Identity, Properties and Uses

Any changes in the following data items from those submitted in the original notification:

a) Proposed uses of the chemical, including concentration in end-use products
b) Import quantity for each product
c) Transportation, packaging and storage
d) Operation description, including disposal
e) Updated exposure scenarios for the environment, workers and the public
f) Any additional physico-chemical data that is available for the notified chemical

- Toxicity

Human Health
Any additional toxicology data that are available for the notified chemical;

Ecotoxicity
Any additional ecotoxicology data that are available for the notified chemical;

- (M)SDS

Copy of (M)SDS for the products, and for the chemical itself (if revised).

The requested data may be provided through the submission of studies (tests conducted on the notified chemical or suitable analogue) or other sources of information.

This report, SN/28, represents the revised assessment for Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine. Where additional data has been provided, it has been incorporated into the report (if necessary) and the implications of the data for the health and environmental risks of the notified chemical considered.

NOTIFICATION CATEGORY
Secondary notification

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: molecular weight, analytical data, degree of purity, impurities, use details, and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for: vapour pressure, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, particle size, and oxidising properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
LTD/1640 (2014)

NOTIFICATION IN OTHER COUNTRIES
USA (2015), Canada (2001), China, EU (2015), Korea, New Zealand, Philippines, and Turkey

2. IDENTITY OF CHEMICAL

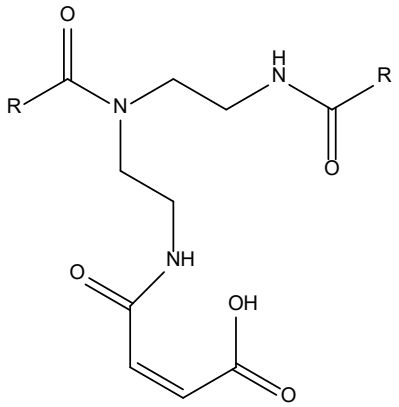
MARKETING NAME(S)
EZ SPOT (contains the notified chemical at ≤ 30% concentration)
EZ MUL NT (contains the notified chemical at ≤ 100% concentration)
INVERMUL NT (contains the notified chemical at ≤ 30% concentration)
INNOVERT Mud System (contains the notified chemical at ≤ 5% concentration)

CAS NUMBER
68990-47-6

CHEMICAL NAME
Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine`

MOLECULAR FORMULA
$C_8H_{23}N_5.C_6H_{18}N_4.C_4H_{13}N_3.C_4H_2O_3$.Unspecified

STRUCTURAL FORMULA



R = alkyl chain from tall oil fatty acid

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference IR and UV-VIS spectra were provided

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: dark coloured solid

Property	Value	Data Source/Justification
Melting Point	> 500 °C	Measured
Boiling Point	> 500 °C at 101.3 kPa	Measured
Density	2,082.5 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 2.53 x10^{-8} kPa at 25 °C	Estimated based on high boiling point
Water Solubility	Not determined	The notified chemical may be dispersible in water based on the structure characteristic of a surfactant.
Hydrolysis as a Function of pH	Not determined	Contains functionalities that may potentially hydrolyse. However, significant hydrolysis is not expected in the environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	log Pow = 3.19	Measured. A chemical with surfactant characteristics is considered to distribute in both water and oil phases.
Adsorption/Desorption	Not determined	The predominantly hydrophobic part of the notified chemical suggests that the chemical has capability to bind to organic matrices in soil.
Dissociation Constant	Not determined	The notified chemical may have functional groups (from reactants) which could dissociate under environmental conditions (pH 4 – 9). Dissociation constants (pKa) of these components range around 4 and 10.
Flash Point	212 °C at 100 kPa (closed cup)	Measured
Flammability	Not determined	Not expected to be flammable based on flash point.
Autoignition Temperature	418 °C	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Predicted negative	Based on chemical structure

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.

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of drilling fluids for both on-shore and off-shore use.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Following is the introduction volume of the notified chemical with respect to the imported products.

EZ SPOT

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

EZ MUL NT

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 260	< 260	< 260	< 260	< 260

INVERMUL NT

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 20	< 20	< 20	< 20	< 20

INNOVERT Mud System

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

PORT OF ENTRY

Adelaide, Melbourne, Perth, Brisbane, and Darwin

TRANSPORTATION, PACKAGING AND STORAGE DETAILS FOR PRODUCTS CONTAINING THE NOTIFIED CHEMICAL

EZ SPOT, EZ MUL NT and INVERMUL NT

The products containing the notified chemical at ≤ 100% concentration will be imported in 55-gallon (~208 L) drums or 1,000 L intermediate bulk containers (IBCs). Prior to transportation, the products containing the notified chemical will be temporarily stored at holding warehouses at entry ports. The product will be transported by truck to on-shore drilling sites or by a combination of trucks and ship to off-shore sites.

INNOVERT Mud System

The product containing the notified chemical at ≤ 5% concentration will be imported in 140-barrel (bbl) (~22,250 L) tanks. Prior to transportation, the product containing the notified chemical will be stored in storage tanks at the rig-site or the Liquid Mud Plant prior to on-shore or off-shore use. The product will be transported by truck to on-shore drilling sites or by a combination of trucks and ship to off-shore sites.

USE

The notified chemical in EZ SPOT, EZ MUL NT, INVERMUL NT and INNOVERT Mud System at ≤ 100% concentration will be used as an additive in drilling fluids in off-shore or on-shore well drilling operations.

OPERATION DESCRIPTION

The notified chemical will be imported into Australia as a component of products at ≤ 100% concentration to be used in oil- or synthetic-based fluid systems, with the exception of EZ SPOT, which may also be used in water-base fluid systems.

There will be no further formulation of the notified chemical. However, during end-use in off-shore or on-shore well drilling operations, the products containing the notified chemical will be mixed with other ingredients and then incorporated into the fluid system. The mixture will then be pumped into the well, where it will disperse within the drilling fluid system. After the completion of drilling operations, the drilling mud containing the notified chemical is expected to be pumped out for disposal, recycling, or re-use for both on-shore and off-shore settings. Most handling and use of the product containing the notified chemical is expected to occur outdoors.

When muds are reconditioned for reuse, as typically done for oil-based muds, the drill cuttings are typically treated in a thermal unit to reclaim as much oil as possible. Most of the notified chemical adhering to the drill cuttings would likely be removed with the liquid phase or thermally degraded during this process.

Used drilling fluids or drill cuttings containing the notified chemical is expected to be disposed in accordance with the local regulations.

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)*
EZ SPOT		
Mud Engineer/Technician	2	4
EZ MUL NT, INVERMUL NT, and INNOVERT Mud System		
Mud Engineer/Technician	4	90
Rig Contractor	6	90

EXPOSURE DETAILS
Exposure of workers to the notified chemical at ≤ 100% concentration during transport and storage will only occur in the event of an accidental release.

There is no reformulation of the notified chemical occurring in Australia prior to transport to the end-use sites. At the end-use sites, dermal, ocular and inhalation exposure of workers to ≤ 100% concentration may occur when mixing the products containing the notified chemical with other components and during pumping, maintenance and cleaning of pumping and mixing equipment. Exposure is expected to be limited by the use of personal protective equipment (PPE) including gloves, protective clothing and goggles or a face shield. Exposure is also expected to be limited by the use of ventilated areas.

Once the well drilling is completed, workers may be exposed to the drilling fluid containing < 0.1-5% notified chemical when it is removed from the well for re-use or disposal.

6.1.2. Public Exposure
The notified chemical is intended only for use in the oil and gas industry. Public exposure to the notified chemical is not expected except in the unlikely event of an accident occurring during road transport. Exposure to the public is therefore expected to be negligible.

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 > 2020 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	evidence of sensitisation
Rat, Combined repeat dose oral toxicity with the reproduction/developmental toxicity screening test	LOAEL 300 mg/kg bw/day (systemic) NOAEL 1000 mg/kg bw/day (reproductive)
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian cell gene mutation test	non genotoxic
Genotoxicity – *in vitro* mammalian chromosome aberration test	non genotoxic

Toxicokinetics.
Based on the molecular weight < 1000 Da and the partition coefficient (log PoW = 3.19), dermal absorption of the notified chemical is possible.

Acute toxicity.
The notified chemical is of low acute oral and dermal toxicity based on studies conducted in rats.

Irritation and sensitisation.
The notified chemical was found to be slightly irritating to skin and eyes based on studies conducted in rabbits.

The notified chemical has structural alerts for skin sensitisation. In a guinea pig maximisation test (GPMT), the notified chemical (at 5% intradermal induction concentration; 25% challenge concentration) was found to be a sensitiser with responses noted in 9/10 and 7/10 animals at 24 and 48 hours after patch removal, respectively.

Repeated dose toxicity.
A dose range finding study in rats at doses of 250, 500 and 1000 mg/kg bw/day was conducted to determine the dosage for the main study; a combined repeated dose (oral) toxicity study with the reproduction/developmental toxicity screening test. The dose finding study did not reveal any major toxicological findings. Based on the data generated from the dose range finding study, the notified chemical was tested in rats at doses of 300, 600 and 1,000 mg/kg bw/day in the main combined repeated dose (oral) toxicity study with the reproduction/developmental toxicity screening test.

In the main study, two rats treated at 600 mg/kg/ bw/day were found dead during the early treatment period. Based on the limited pathological evaluation of these decedents, no cause of death could be determined for the female, and gavaging error was considered to be the probable cause of death for the male.

In the female and male reproductive organs, no histopathological lesions considered to be test item-related were noted. Based on clinical observations, three females had been recorded not to be pregnant during the study and showed normal sexual cycling activity in histopathology.

Test item-related histopathological changes were restricted to the lung. Multifocal subacute bronchopneumonia, characterized by peribronchial foci of prominent fibrosis, with re-epithelialization, infiltration with mononuclear cells, histiocytes and occasional multinucleated cells, was observed in a small proportion of treated males and females of all dose groups, without dose relationship. In addition, a mild amount of intrahistiocytic black material was seen in the lung of each one male treated at 300 or 1000 mg/kg bw/day.

Based on the results found in this study, no effects were reported on reproductive/developmental toxicity parameters measured in the study. There were also no effects reported on general toxicity parameters except for the reported macroscopic/microscopic lung changes.

For reproductive/developmental toxicity the No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on no treatment related effects on reproductive/developmental parameters at the highest dose tested.

For systemic toxicity a Low-Observed-Adverse-Effect-Level (LOAEL) of 300 mg/kg bw/day was established based on histopathological lung changes at all doses tested.

Mutagenicity/Genotoxicity.
The notified chemical was found to be non-mutagenic in an *in vitro* bacterial reverse mutation study. The notified chemical was also found to be non-genotoxic in an *in vitro* chromosome aberration test and in an *in vitro* cell mutation assay using Chinese hamster lung fibroblasts and mouse lymphoma cells, respectively.

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

Hazard classification	*Hazard statement*
Skin sensitisation (Category 1)	H317-May cause an allergic skin reaction

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:

R43: May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified chemical is a skin sensitiser. Therefore, workers at the end-use sites may be at risk of sensitisation effects when handling the notified chemical. The notified chemical is also slightly irritating to the eyes and may cause systemic effects. However, given the outdoor nature of the operations, the short exposure duration and the use of PPE (e.g. impervious gloves, goggles, coveralls and a face shield, if necessary), exposure to the notified chemical during use and handling is expected to be minimised.

Therefore, provided adequate control measures are in place to minimise worker exposure and appropriate PPE are used, the risk to workers from the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

The risk to the public associated with the notified chemical is not considered to be unreasonable due to negligible exposure.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of a finished solvent based product and will not be reformulated in Australia. Therefore, no environmental releases are expected from manufacturing or reformulation in Australia. Accidental spills during transport are expected to be handled by physical containment, collection and subsequent safe disposal.

RELEASE OF CHEMICAL FROM USE

The notified chemical is reported to have a number of uses with varying degrees of release to the environment. The uses for the notified chemical are listed in the table below.

Product	Operation Description
EZ SPOT	EZ SPOT will be used to free up drilling pipes that were blocked during drilling for oil and gas wells. It can be used in oil-, synthetic-, and water-based fluid systems.
EZ MUL NT	EZ MUL NT will be used routinely as a secondary emulsifier, as an invert emulsifier, and an oil-wetting agent for oil- and paraffin-based drilling fluid systems, to help reduce the flow properties of invert emulsions.
INVERMUL NT	INVERMUL NT will be used routinely as a primary emulsifier designed for oil- and paraffin-based drilling fluid systems. It helps stabilize emulsions, aids suspension properties, and helps reduce HPHT filtration.
INNOVERT Mud System	INNOVERT Mud System can be blended with other drilling fluid and is used only under special circumstances in areas where paraffin/mineral oil is the preferred base oil.

The notified chemical in EZ Spot is expected to be released to the marine environment as it is used in water based mud. The other products are not expected to be significantly released to the marine environment.

The notified chemical is a component of the product EZ SPOT, which is to be used off-shore and on-shore to free up blocked drilling pipes incurred during drilling for oil and gas wells. The notified chemical is mixed into a volume of fluid, known as a pill, which is pumped into position in the well bore where the drill pipe is lodged against the well bore. Stuck pipe incidents occur in less than 1% of drilled wells.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical will share the fate of the drilling mud mixture, and may be re-used (if synthetic or oil-based) or treated and discharged in compliance with local regulations (if water-based). For off-shore application, the used water-based drilling mud may be disposed of directly to the ocean water on site. For on-shore application, if disposal is the only option, used drilling muds are expected to be sent to a registered disposal facility, which is most likely a landfill. Furthermore, solids which have been generated on-shore through mechanical separation to recondition the fluid may also be sent to a disposal facility (the fluid is re-used). As the

drilling system will be re-collected or sent to a disposal facility, it is unlikely that the notified chemical will reach the aquatic environment. Residue of the notified chemical in empty containers may share the fate of the container and be disposed of to landfill, or be washed to sewer where containers are rinsed before recycling.

7.1.2. Environmental Fate

A ready biodegradation test for the notified chemical indicates that the notified chemical is not readily biodegradable in the marine environment but can significantly biodegrade in the ocean water. For the details of the environmental fate studies please refer to Appendix B. The molecular weight is indicated by the notifier to be > 500 Da. The potential for bioaccumulation in aquatic organisms cannot be excluded. However, the expected biodegradation property can reduce the potential to be accumulative in aquatic organisms.

For off-shore use and within water-based drilling fluid systems, some of the notified chemical is expected to be released to the ocean, followed by deposition into the sediment due to the presence of predominant amount of hydrophobic segments in the molecule, and degradation. For on-shore use, the notified chemical is expected to be most likely released to landfill, and release to the aquatic environment is not considered to be significant. In landfill, the notified chemical is not expected to leach given the presence of cationic and hydrophobic components that are likely to absorb to soil. In water or soil, the notified chemical is expected to be degraded via biotic or abiotic pathways, forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Off-shore

The highest concentrations of the notified chemical 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). As indicated previously, the use of the notified chemical does not occur frequently since stuck pipe incidents occur in less than 1% of drilled wells.

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 chemical 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 Predicted Environmental Concentration (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 chemical 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}). The values for volume of mud discharged will be 20-30 m^3, provided by the notifier, and the dilution factor has not been provided for operations under Australian conditions. Hence, the default value for D_{batch} (7.7×10^{-5}) as specified in the CHARM model for the batch-wise discharge scenario has been used for this calculation (Thatcher et al., 2005, p. 46). Based on these default values, and the worst case discharge of < 10 kg of notified chemical in a single batch of used mud, the $PEC_{water,batch}$ for the notified chemicals is calculated to be < 0.05 mg/L. The details for this calculation, including the data used, are exempt information.

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. However, based on the surfactant character of the notified chemical, a significant fraction of the discharged mass of this chemical is expected to remain associated with the insoluble minerals and other solids discharged overboard. This fraction of the notified chemical is therefore expected to deposit on the sea floor beneath the discharge point along with the mud and cuttings. The concentration of the notified chemical in sediment ($PEC_{sediment}$) is therefore of potential significance.

The $PEC_{sediment}$ for a batch-wise discharge scenario is not calculated in the CHARM model because there is assumed to be insufficient time to allow the establishment of equilibrium between the high short-term levels of chemicals in the water column arising from batch-wise release of muds and the levels of these chemicals in sediments near the discharge point. Thus, in the CHARM model, the calculation of $PEC_{sediment}$ is based on a continuous discharge scenario (Thatcher et al., 2005, p. 73). This scenario cannot be evaluated for Australia as

the specific model parameters are not available and the default values for some key parameters are specific to drilling operations in the North Sea. However, an estimate of the $PEC_{sediment}$ can be made in accordance with the CHARM model assuming that the greatest effect of the chemical will occur within a radius (r) of 500 m from the discharge line. In this case, the total volume of sediment affected is $\pi r^2 d$. If the depth of sediment (d) is taken to be 5 cm, the resulting volume of affected sediment is 39 270 m^3. If the density of the sediment is approximately 1200 kg/m^3 (default value), then the mass of affected sediment is 47100 tonnes. If it is further assumed for a worst case that 50% of the discharged mass of notified chemical in a batch of used mud, which is < 5 kg, is deposited in this layer of sediment, then the $PEC_{sediment}$ for the notified chemical in the benthic system is estimated to be < 0.1 mg/kg. The details for this calculation, including the data used, are exempt information.

The Predicted Environmental Concentration (PEC) from oil-based muds is expected to be lower than that for the water-based since the liquids containing part of the notified chemical will be recycled for re-use. Therefore, the PEC for oil-based drilling muds has not been calculated.

On-shore

The PEC for on-shore use is not calculated given no significant release of the notified chemical to the aquatic environment is expected based on the proposed use pattern.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish (96 h LL50)	> 1000 mg/L (WAF)	Not harmful to fish
Copepod (48 h EL50)	> 2000 mg/L (WAF)	Not harmful to aquatic invertebrate
Algal (72 h E_rL50)	23.8 mg/L (WAF)	Harmful to algae
Amphipod (10 d LC50)	> 10,000 mg/kg dry weight	Not harmful to sediment re-Worker

WAF = water accommodated fraction

The notified chemical is considered to be harmful to aquatic organisms based on the 72 h endpoint to alga. The notified chemical is not considered to be readily biodegradable. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified chemical is formally classified as Acute Category 3, harmful to aquatic organisms, on an acute basis, and Chronic Category 3, harmful to aquatic organisms with long lasting effects, on a long term basis.

7.2.1. Predicted No-Effect Concentration

The marine PNEC, calculated for the use of the notified chemical in off-shore drilling fluids, was determined by using the endpoint for the most sensitive species from the reported results (Algae, E_rL50). An assessment factor of 100 was used as full study reports were available for three trophic levels.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
72 h E_rL50 for alga	23.8	mg/L
Assessment Factor	100	
PNEC:	0.238	mg/L

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) for off-shore use has been calculated below:

Risk Assessment	PEC mg/L	PNEC mg/L	Q
Q - Ocean	< 0.05	0.238	**< 0.21**

No deposition to the sediment or biodegradation has been considered. The Risk Quotient for on-shore use was not calculated given the PEC has not been calculated due to the expected low release to aquatic environment. This plus the reported low toxicity suggest that the notified chemical is not expected to pose an unacceptable risk to fresh water organisms.

Based on the assessed use pattern and the expected low toxicity to aquatic organisms, the notified chemical is not expected to pose an unreasonable risk to the seawater and freshwater aquatic environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point > 500 °C

Method	OECD TG 102 (1995) Commission Directive 92/69/EEC Part A: Methods for the Determination of Physico-Chemical Properties A.1 "Melting/Freezing Temperature"
Remarks	Siwolloboff and DSC (Differential Scanning Calorimetry) method
Test Facility	Confidential

Boiling Point > 500 °C

Method	OECD TG 103 (1995) Commission Directive 92/69/EEC Part A: Methods for the Determination of Physico-Chemical Properties A.2 "Boiling Temperature"
Remarks	Siwolloboff and DSC method
Test Facility	Confidential

Density 2082.5 kg/m^3 at 20 °C

Method	OECD TG 109 (Density of Liquids and Solids). Commission Directive 92/69/EEC A.3 Relative Density. CIPAC (Collaborative International Pesticides Analytical Council), Physico-chemical Methods for Technical and Formulated Pesticides, MT 3.2 "Specific gravity, density and weight per millilitre - Pyknometer method"
Remarks	Due to the high viscosity of the test item, the pyknometer method was not applied; therefore 50 ml volumetric flasks were employed to obtain a representative density value of the notified chemical at 20 °C.
Test Facility	Confidential

Flash Point 212 °C at 100.1 kPa

Method	EC Council Regulation No 440/2008 A.9 Flash Point.
Test Facility	Confidential

Autoignition Temperature 418 °C (closed cup)

Method	EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility	Confidential

Explosive Properties

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	The tests for *Thermal sensitivity (effect of a flame), Mechanical sensitivity (shock)* and *mechanical sensitivity (friction)* were performed under the EU Method A.14 method. The test substance was not sensitive to impact, friction or conditions of intense heat and defined confinement, and was considered to be not explosive.
Test Facility	Confidential

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 401 Acute Oral Toxicity.
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Acetone
- Remarks - Method: No significant protocol deviation

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	2020	1/10

- LD50: > 2020 mg/kg bw
- Signs of Toxicity: One female died during the study. Clinical signs included activity decrease, diarrhea, polyuria, red fluid around anus and soft feces, which were no longer evident in surviving animals by day 1. Gasping, respiratory chirp, and swollen/stained face were observed only in the animal that died on test. There was no effect on body weight gain in surviving animals.
- Effects in Organs: The gross necropsy on the animal that died on test revealed stained/wet/matted fur; tail tip missing; discolored lungs, liver and contents of the stomach and small intestine; gas in the stomach/small intestine and empty large intestine. The gross necropsy on 6 of 9 animals surviving to termination of the study revealed discolored heart and/or lungs; remaining three showed no observable abnormalities.
- Remarks - Results:

CONCLUSION: The notified chemical is of low toxicity *via* the oral route.

TEST FACILITY: Confidential

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.
EPA OPPTS 870.1200-Acute Dermal Toxicity, EPA 712-C-98-192, 1998
- Species/Strain: Rat/Wister Crl: WI(Han)
- Vehicle: Test substance moistened with cotton seed oil.
- Type of dressing: Semi-occlusive.
- Remarks - Method: The test substance was heated up to 80 ºC before administration. No other significant protocol deviation.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5/sex	2000	None

- LD50: > 2000 mg/kg bw
- Signs of Toxicity - Local: Erythema (grade 1) was observed in 3 out of 5 female animals and 2 out of 5 male animals. Desquamations were observed in all animals. Eschar was observed in 1 out of 5 female and 3 out of 5 male animals. Scratches were

	observed in 3 out of 5 male animals. All signs of irritation were reversible within the observation period.
Signs of Toxicity - Systemic	There were no deaths or test-substance related clinical signs. A slightly low bodyweight gain was evident in one female. All other animals were considered to have achieved satisfactory bodyweight gains throughout the study.
Effects in Organs	There were no test-substance related effects on organs.
CONCLUSION	The notified chemical is of low toxicity *via* the dermal route.
TEST FACILITY	Confidential

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (males)
Vehicle	None
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	No significant protocol deviation. Exposure times 3 minutes, 1 hour and 4 hours.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.3	0.3	0.7	1	< 72 h	0
Oedema	0	0.3	0	1	< 48 h	0

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

Remarks - Results	No changes were seen at the treatment sites where the test substance was applied for 3 minutes or 1 hour. At the sites exposed for 4 hours, very slight erythema (grade 1) was observed in all animals and very slight oedema (grade 1) was observed in one animal at the 24 h observation period. At the 48 hour observation period slight erythema persisted in one single animal. All signs of irritation were resolved at the 72 hour observation period. There were no deaths or test substance-related clinical signs or remarkable body weight changes during the study period.
CONCLUSION	The notified chemical is slightly irritating to the skin.
TEST FACILITY	Confidential

B.4. Irritation – eye

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. Annex to EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (males)
Observation Period	72 hours
Remarks - Method	Conjunctival discharge was not monitored.

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	1	0.3	1	2	< 72 h	0
Conjunctiva: chemosis	0.3	0	0	1	< 48 h	0
Conjunctiva: discharge	-	-	-	-	-	-
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results: Slight to moderate conjunctival irritation was observed in all animals which was fully resolved at the 72 observation period. No iridial or corneal effects were observed.

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

TEST FACILITY: Confidential

B.5. Skin sensitisation

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 406 Skin Sensitisation - Guinea Pig Maximisation Test
EC No. 440/2008, L 142, Annex Part B, 30 May 2008
EPA OPPTS 870.2600-Skin Sensitisation, EPA 712-C-03-197, 2003

Species/Strain: Guinea pig/Crl:HA

PRELIMINARY STUDY: Maximum Non-irritating Concentration:
intradermal: 2.5% in cottonseed oil
topical: 25% in cottonseed oil

MAIN STUDY

Number of Animals: Test Group: 10 female Control Group: 5 female

INDUCTION PHASE: Induction Concentration:
intradermal: 5% in cottonseed oil
topical: 50% in cottonseed oil

Signs of Irritation: Intradermal injection: Slight irritation was seen in all the test animals at sites receiving the test substance at 5% concentration (v/v) in both cottonseed oil and in a 1:1 mixture (v/v) FCA/physiological saline 0.9% NaCl. Slight irritation was also observed at site receiving a 1:1 mixture (v/v) FCA/physiological saline 0.9% NaCl. Slight irritation was observed in control animals receiving 1:1 mixture (v/v) FCA/physiological saline 0.9% NaCl.

Topical induction: The test sites were pre-treated with 10% sodium lauryl sulphate 24-hours before topical induction. Eschar was observed in four out of ten test animals after 24 hours of topical induction. No erythema was observed in control animals following topical induction.

CHALLENGE PHASE

1st challenge: topical: 25% in cottonseed oil

Remarks - Method: No significant protocol deviation

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*	
		24 h	*48 h*

Test Group	25%	9	7
Control Group	25%	0	0

Remarks - Results: Erythema and oedema were observed in all test animals during the observation period. Skin reactions were noted in 9/10 and 7/10 animals at 24 and 48 hours after patch removal, respectively. There was no effect on the body weight gain of the animals.

CONCLUSION: There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: Confidential

B.6. Repeat dose toxicity

TEST SUBSTANCE: Notified chemical

METHOD: Dose Range Finding Study for Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Rat (OECD TG 422)

Species/Strain: Rats/Wistar Crl:WI (Han)
Route of Administration: Oral – gavage
Exposure Information: Total exposure days: 28 days (males), 38 days (females)
Dose regimen: 7 days per week
Vehicle: Corn oil
Remarks - Method: No significant protocol deviation

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	3/sex	0	0
low dose	3/sex	250	1
mid dose	3/sex	500	2
high dose	3/sex	1000	0

Mortality and Time to Death

No test item related mortality was observed during the entire study period. Two males from low and mid dose group and one female from mid dose group were found dead due to gavaging error.

Two pups were found dead from females of control group on post natal day (PND) 1.

Clinical Observations

No test item related clinical observations were observed in males and females during the study. The body weight development was higher in both male and female animals treated with the test substance at doses of 250 mg/kg bw/day. However, the body weight development was lower in males treated with mid dose and high dose of the test substance compared to controls whereas it was lower and higher in females treated with high dose and mid dose of the test substance, respectively, compared to control. The body weight development was lower and higher during second week of premating and lactation period and during the entire gestation period, respectively, compared to control. There was no dose-dependent effect of the test substance on the food consumption of the test animals.

There was no treatment related effect observed on precoital interval, duration of gestation, the group mean number of corpora lutea, number of implantation, number of live pups, percent pre and post implantation loss and group litter.

Effects in Organs

Gross necropsy findings of the two found dead pubs revealed no specific findings. No treatment related findings were observed in surviving males, females and pups.

The organ weights revealed no treatment related effects in males. However, biologically significant differences

were observed for absolute and relative weights of ovaries and uterus (with cervix) in high dose group compared with the controls in females.

Remarks – Results
No major toxicological findings were observed during the study at all doses.

CONCLUSION
Based on the results of this dose range finding study, dosages of 300, 600 and 1000 mg/kg bw/day were considered for the main study.

TEST FACILITY Confidential

B.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

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

Species/Strain	Rats/Wistar Crl:WI (Han)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28/29 days (males; pre-mating 1-14, post mating 1-14) 38 days (females; pre-mating 1-14, gestation 0-20, lactation 0-4) Dose regimen: 7 days per week
Vehicle	Corn oil
Remarks - Method	No significant protocol deviation.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10/sex	0	0
low dose	10/sex	300	0
mid dose	10/sex	600	2
high dose	10/sex	1000	0

Mortality and Time to Death
Based on the limited histopathological evaluation of the two decedents treated at 600 mg/kg/day, no cause of death could be determined for female animal. Histopathological lung findings in male animal (intra-alveolar eosinophilic material, perivascular edema/hemorrhage and diffuse congestion) suggest gavaging error as its cause of death. No test item related mortalities and effect on functional and behavioural endpoints were observed in male and female animals during the entire study period.

Clinical Observations
Statistical analysis of reproduction and litter data revealed no treatment related effect on group mean litter weight, number of males and females, total litter weight, male and female litter weights on post natal day (PND) 0 and PND 4, percent pre implantation loss, post implantation loss, total number of pups born, sex ratio, live pups, still birth and runt on PND 0, total no of live pups and sex ratio on PND 0 and 4, precoital interval, number of corporal lutea, number of implantation sites when compared to controls.

Statistically significant deviation was observed for % pre-implantation loss and group mean litter weight (PND 4) in mid dose and high dose groups compared to corresponding controls. However, the study authors considered this deviation to be incidental.

The body weight and food consumption in both males and females remained unaffected due to treatment when compared to the corresponding controls. However, statistical significant deviation was observed for body weight change in females during premating days 7 to 14 in animals administered with mid dose.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
In males and females, statistically no significant effect was observed for any of the haematological and clinical

biochemistry parameters when compared to their corresponding control. However, there were some individual deviations observed from the historical control range for the respective haematological parameters (WBC, RBC, and HGB in females and MCH in males). The individual and mean values observed for the clinical biochemistry parameters evaluated were also within the range except for cholesterol, TP, ALBB and K. These deviations from the historical control range were considered incidental by the study authors.

Urinalysis in five randomly selected males from each group did not reveal any test item related effect.

Effects in Organs

At necropsy, macroscopic changes associated with liver, lung and epididymides were observed in most of the animals in all groups. Microscopic changes were noted only in lungs. No test item related changes were observed in pups at necropsy or death during the study. Statistically no significant changes were observed in the absolute and relative organ weights in males of all treatment groups when compared to controls. However, in females, statistically significant differences were observed in relative brain weight in low dose and high dose groups compared to controls.

Reproductive organs:

In the female and male reproductive organs, no histopathological lesions considered to be test item-related were noted. Histologically, female reproductive organs showed physiological postpartum morphology in most surviving animals. The number of large corpora lutea in the ovaries was essentially similar in all study groups. Based on clinical observations, each one female treated at 0, 300 or 600 mg/kg/day was found not to be pregnant at terminal sacrifice, and reproductive organ histomorphology of these animals indicate normal sexual cycling activity.

In the male reproductive organs, a minimal number of unilateral atrophic tubules in the testis were seen in one male treated at 600 mg/kg/day without dose relationship and were considered to be incidental. In the epididymis, spermatic granuloma was observed in a small number of treated males and in one control, corroborating the macroscopic finding of spots on the epididymis, and was considered a spontaneous lesion. There were also incidental infiltrates with inflammatory cells in the prostate gland.

Other organs:

Test item-related histopathological changes were seen in the lung of a small proportion of treated males and females of all dose groups, without dose relationship. The changes included multifocal subacute bronchopneumonia, characterized by peribronchial foci of prominent fibrosis, with re-epithelialization, infiltration with mononuclear cells, histiocytes and occasional multinucleated cells. In some animals the lesions contained also foci of necrosis, and in some animals the pulmonary changes were less well organised and contained larger numbers of mixed cells. The mechanism of this lesion was not clear to the study authors. A mild amount of intrahistiocytic black material was seen in the lung of each one male treated at 300 or 1000 mg/kg bw/day. All other histopathological changes seen in this study were considered to be incidental in origin and/or within the range of expected changes for rats of this age and strain kept under laboratory conditions.

Remarks – Results

Two rats treated at 600 mg/kg bw/day were found dead during the early treatment period. Based on limited pathological evaluation of these decedents, no cause of death could be determined for the female, and gavaging error was considered to be the probable cause of death for the male. In the female and male reproductive organs, no histopathological lesions considered to be test item related were observed. Based on clinical observations, three females had been recorded not to be pregnant during the study and showed normal sexual cycling in histopathology.

Test item related histopathological changes were restricted to the lungs. Multifocal subacute bronchopneumonia, characterised by the periblochial foci of prominent fibrosis, with reepithelialisation, infiltration with mononuclear cells, histiocytic and occasional multinucleated cells, was observed in a small proportion of treated males and females of all dose groups, without dose relationship. In addition, a mild amount of intrahistiocytic black material was seen in the lung of each one male treated at 300 or 1000 mg/kg/day.

CONCLUSION

For reproductive/developmental toxicity the No Observed (Adverse) Effect Level (NO(A)EL) was established as 1000 mg/kg bw/day in this study, based on no treatment related effects on reproductive/developmental parameters at the highest dose tested.

For systemic toxicity a Low-Observed-Adverse-Effect-Level (LOAEL) of 300 mg/kg bw/day was established based on histopathological lung changes at all doses tested.

TEST FACILITY Confidential

B.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

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

Species/Strain	*S. typhimurium*: TA1535, TA98, TA100, TA102, TA97a
Metabolic Activation System	S9 fraction from Aroclor-induced rat liver
Concentration Range in Main Test	a) With and without metabolic activation: 80, 100, 300, 800, 1000, 3000 and 5000 µg/plate (test 1) b) With and without metabolic activation: 30, 80, 100, 300, 800, 1000 and 3000 µg/plate (test 2)
Vehicle	1-Methyl-2-pyrollidone
Remarks - Method	No significant protocol deviation. Lower dose levels were used in Test 2 to better visualise colonies as the test substance was insoluble at ≥ 3000 µg/plate. The preliminary toxicity test was performed on tester strains TA98 and TA100.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 5000	≥ 3000	≥ 3000	Negative
Test 2		≥ 3000	> 3000	Negative
Present				
Test 1	≥ 5000	≥ 1000	≥ 3000	Negative
Test 2		≥ 1000	≥ 3000	Negative

Remarks - Results No significant increase in revertant colony numbers of any of the five tester strains was observed at any dose level in the presence or absence of metabolic activation.

Negative controls were within the historical limits and positive controls demonstrated the sensitivity of the study.

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

TEST FACILITY Confidential

B.9. Genotoxicity – *in vitro*

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 *In vitro* Mammalian Cell Gene Mutation Test.
EC Directive 2000/32/EC B.17 Mutagenicity - *In vitro* Mammalian Cell Gene Mutation Test.

	EPA OPPTS 870.5300 – *In Vitro* Mammalian Cell Gene Mutation test, EPA 712-98-221, 1998
Cell Type/Cell Line	Mouse Lymphoma cells/ L5178Y
Metabolic Activation System	S9 microsomal fraction from β-naphthoflavone/phenobarbital-induced rat liver
Vehicle	Cell culture medium
Remarks - Method	No significant protocol deviation

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	20, 50, 100, 200, 400, 500, 600, 700	4 h	72 h	11-14 d
Test 2	2, 10, 40, 70, 100, 140, 180, 220	24 h	48 h	11-14 d
Present				
Test 1	200, 400, 600, 800, 1000, 1300, 1500, 1700	4 h	72 h	11-14 d
Test 2	10, 30, 75, 150, 300, 500, 700, 1000	4 h	72 h	11-14 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	≥ 625	≥ 500	≥ 20	Negative
Test 2		≥ 100	≥ 2	Negative
Present				
Test 1	≥ 1250	≥ 1300	≥ 200	Negative
Test 2		≥ 1000	≥ 75	Negative

Remarks - Results	No significant increases in mutation frequency were observed in the absence or presence of metabolic activation. The results from the negative and positive controls demonstrated the sensitivity of the test.
CONCLUSION	The notified chemical was not clastogenic to mouse lymphoma L5178Y cell lines treated *in vitro* under the conditions of the test.
TEST FACILITY	Confidential

B.10. Genotoxicity – *in vitro*

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test. EC Directive 440/2008 B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test. EPA OPPTS 870.5375- *In Vitro* Mammalian Chromosome Aberration Test, EPA 712-C-98-223, 1998
Cell Type/Cell Line	Chinese Hamster V79 cells
Metabolic Activation System	S9 microsomal fraction from β-naphthoflavone/phenobarbital-induced rat liver
Vehicle	Cell culture medium
Remarks - Method	No significant protocol deviation

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	125, 250, 500, 1000*, 2500*, 5000*	4 h	20 h
Test 2	31.3, 62.5, 125, 250*, 500*, 1000*, 2500, 5000	20 h	20 h

Present			
Test 1	125, 250, 500, 1000*, 2500*, 5000*	4 h	20 h
Test 2	500, 1000, 2000, 3000*, 4000*, 5000*	4 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 5000	> 5000	> 1000	Negative
Test 2		≥ 1000	> 250	Negative
Present				
Test 1	> 5000	> 5000	> 1000	Negative
Test 2		> 5000	> 3000	Negative

Remarks - Results

There were no statistically significant increases in the frequency of cells with chromosomal aberrations in either test, with or without metabolic activation.

The negative controls were within the historical range and the positive controls demonstrated the sensitivity of the test.

CONCLUSION

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

TEST FACILITY

Confidential

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	Aerobic Biodegradation in Seawater using the MARINE BODIS ISO/TC 147/SC 5/WG 4N 141
Inoculum	Natural sea water containing microorganisms fortified with mineral nutrients, salinity 34-37‰
Exposure Period	56 days
Auxiliary Solvent	Silica powder was used as inert support medium for the test substance
Analytical Monitoring	Biological oxygen demand (BOD)
Remarks - Method	The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported. The test substance was coated on inert silica power before the test. In addition to tests with the notified chemical, a reference control using sodium benzoate, a reference oil (olefin oil) control, a toxicity control, and a blank control were established in triplicates.

RESULTS

Notified chemical		*Sodium benzoate*		*Reference oil*	
Day	*% Degradation*	*Day*	*% Degradation*	*Day*	*% Degradation*
14	18	7	69	7	1
28	34	28	100	28	44
56	71	56	100	56	55

Remarks - Results	All validity criteria for the test were satisfied. The reference compound, sodium benzoate, reached the 60% pass level by day 7 indicating the suitability of the inoculum. The toxicity control exceeded 25% biodegradation within 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The test conditions do not vary significantly to the OECD TG 306. The degree of degradation of the test substance was 34% after 28 days. Therefore, the test substance is not considered to be readily biodegradable based on the test outcome.
CONCLUSION	The notified chemical is not considered to be readily biodegradable in the marine water
TEST FACILITY	Opus (2007)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	Semi-Static Acute Toxicity Test Following Paris Commission (PARCOM) Method (1995) and OECD TG 203Guidelines
Species	Juvenile Turbot (*Scophthalmus maximus*)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Water Hardness	31 ‰
Analytical Monitoring	None reported
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. Water Accommodated Fractions (WAFs) containing the test substance for all treatment concentrations were prepared in artificial seawater. The mixture was mixed overnight and following a 4 hour settling period, supernatant was removed and used as treatment solution.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		7			0		
100.0		7			0		
177.8		7			0		
316.2		7			0		
562.3		7			0		
1000		7			0		

LL50	>1000 mg/L at 96 hours (WAF)
NOEL	≥1000 mg/L at 96 hours (WAF)
Remarks – Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to fish
TEST FACILITY	STL (2004a)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	ISO 14669:1999 (E) Water Quality – Determination of Acute Lethal Toxicity to Marine Copepods
Species	*Acartia tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	34.5 g/L
Analytical Monitoring	None reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The above stated test guideline is very similar to OECD TG 202. Water Accommodated Fractions (WAFs) containing the test substance for all treatment concentrations were prepared in artificial seawater. The mixture was mixed overnight and following a 4 hour settling period, the central portion was removed and used as treatment solution.

RESULTS

Nominal Concentration (mg/L)	*Number of A. tonsa*	*Cumulative % Immobilised 48 h*
Control	20	10
200	20	15
355.6	20	40
632.4	20	35
1124.7	20	45
2000.0	20	40

LL50	> 2000 mg/L at 48 hours (WAF)
NOEL	632.5 mg/L at 48 hours (WAF)
Remarks - Results	All validity criteria for the test were satisfied. There was no evidence of a dose response in this study. The statistical programme, Toxcalc, was used to calculate the endpoints.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates
TEST FACILITY	STL (2003a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	EN ISO 10253, detailed in STL Runcorn SOP III.19. – Static
Species	Marine Alga (*Skeletonema costatum*)
Exposure Period	72 hours
Concentration Range	Nominal: 10.0, 17.8, 31.6, 56.2, 100.0 mg/L
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The above test guideline is similar to the OECD TG 201 Alga, Growth Inhibition Test. Water Accommodated Fractions (WAFs) containing the test substance for all treatment concentrations were prepared in Guillard's f/2 + Si test media. The mixtures were mixed by spinning and were allowed to settle. The spinning period was not provided in the study. The clear central portion was siphoned and used as treatment solution.

RESULTS

Growth	
E_rL50 (72 h; mg/L)(WAF)	*NOE_rL (72 h; mg/L)(WAF)*
23.8	*10*

Remarks - Results	All validity criteria for the test were satisfied. The statistical programme, Toxcalc, was used to calculate the endpoints.
CONCLUSION	The notified chemical is harmful to algae
TEST FACILITY	STL (2004b)

C.2.4. Toxicity to marine benthic organisms

TEST SUBSTANCE	Notified chemical
METHOD	A Sediment Bioassay using An Amphipod *Corophium* sp. Oslo and Paris Commission (PARCOM) Method (1994) – Static-test
Species	Sediment Re-Worker (*Corophium volutator*)
Exposure Period	10 day
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Nominal Concentration (mg/kg; dry weight)	*Number of C. volutator*	*Percent mortalities*
Control	100	8
1000.0	60	13
1778.3	30	5
3162.3	30	12
5623.4	30	15
10,000.0	30	3

LC50	> 10,000 mg/kg (dry weight) at 10 days
NOEC	10,000 mg/kg (dry weight) at 10 days
Remarks - Results	All validity criteria for the test were satisfied. The endpoints were calculated based on the dry weight of the sediment used.
CONCLUSION	The notified polymer is not harmful to marine sediment re-Worker.
TEST FACILITY	STL (2003b)

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