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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in Quik-Free and Geltone II

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

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/1509	Halliburton Australia Pty Ltd	Chemical in Quik-Free and Geltone II	ND*	≤ 10 tonnes per annum	Viscosity-increasing agent in oil and gas drilling fluids

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However the notified chemical contains an impurity at up to 5% concentration that has been associated with carcinogenic effects via the inhalation route.

Human health risk assessment
Provide that control measures are in place to minimise worker exposure to the notified chemical including the use of personal protective equipment (particularly respiratory protection) and ventilated environments, 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

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 where dust or aerosols are generated:
  - Local exhaust ventilation and/or appropriate extraction systems where possible;
  - Good general ventilation

- 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 in products:
  - Avoid contact with skin and eyes
  - Use of low-dust handling techniques
  - Observance of relevant exposure standards (e.g. for silica and atmospheric dust)

- 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 the notified chemical in products:
  - Coveralls, impervious gloves, goggles
  - Respiratory protection where dusts or aerosols of the notified chemical are generated

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

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

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

Disposal

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

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent 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
  – information becomes available on the presence of nano-sized components in the notified chemical;

or

(2) Under Section 64(2) of the Act; if
  – the function or use of the chemical has changed from viscosity-increasing agent in oil and gas drilling fluids, 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 notified chemical (and products containing the notified chemical) provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Halliburton Australia Pty Ltd (ABN: 73 009 000 775)
Level 17
444 Queen St
Brisbane QLD 4000

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, degree of purity, impurities, use details, import volume and references to analogues.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical properties except partition co-efficient, all toxicological endpoints, and bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU, Canada, China, Korea, New Zealand, Philippines, USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Quik-Free (product containing the notified chemical)
Geltone II (product containing the notified chemical)

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
None provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Tan powder with slight odour (Geltone II which contains 60-100% of the notified chemical); light brown to yellow liquid (Quik-Free which contains 1-5% of the notified chemical).

Property	Value	Data Source/Justification
Melting Point/Freezing Point	ca. 180°C (organic portion)	Analogue
Boiling Point	Substance remained in powder form at all temperatures before	Analogue

	decomposition	
Density	Not determined	-
Vapour Pressure	Not determined	Negligible up to 200°C according to the notifier.
Water Solubility	0.34% (w/v)	Measured. A low water solubility is expected based on the structural information
Hydrolysis as a Function of pH	Not determined	Contains no readily hydrolysable chemical groups
Partition Coefficient (n-octanol/water)	$logP_{OW}$ = -0.1548	Measured
Adsorption/Desorption	Not determined	The notified chemical is expected to associate with soils and sediments given it is insoluble in water and has a high molecular weight.
Dissociation Constant	Not determined	The notified chemical contains organic components having cationic functionalities. However, dissociation is not a concern as the components are tightly bound to inorganic matter.
Particle Size	Not determined	-
Flash Point	Not feasible or applicable	Analogue
Flammability	Not determined	Unlikely to be flammable based on physical properties of analogue
Autoignition Temperature	Not determined	Unlikely to be flammable based on physical properties of analogue
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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. Organic dust in the presence of an ignition source can be explosive in high concentrations.

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 will be imported as a component of products: Quick-Free (containing up to 5% concentration) and Geltone II (containing up to 100% concentration).

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

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

PORT OF ENTRY
Fremantle, Melbourne and Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS
Halliburton Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The product Quik-Free containing the notified chemical at ≤ 5% will be imported in 55 gallon drums and transported by truck to on-shore drilling sites or by a combination of trucks and ship to off-shore sites.

The product Geltone II containing ≤ 100% of the notified chemical will be imported in 50 pound (22.7 kg) sacks on shrink-wrapped pallets and transported by truck to on-shore drilling sites or by a combination of trucks and ship to off-shore sites.

USE
The notified chemical will be used as viscosity-increasing agents to alleviate blocked or stuck drilling pipes in oil and gas wells. Quik-Free is a viscosity-increasing fluid used at oil and gas wells, specifically to alleviate blocked or stuck drilling pipes.
Geltone II may be used alone to provide viscosity in synthetic-based mud systems or used with Quik-Free to alleviate blocked or stuck drilling pipes.

OPERATION DESCRIPTION
End-use
Products containing the notified chemical at up to 100% are transported via road and/or sea for end-use in on-shore and off-shore drilling.

The product Quik-Free (≤5% of the notified chemical), will be incorporated into the active lubricating drilling fluid at a final concentration of 0.67% in the drilling mud in the event of a blocked pipe. Once the pipe is free, the product containing the notified chemical incorporates into the active lubricating drilling fluid. After drilling operations, the drilling mud will be pumped out from the well-hole for disposal.

The product Geltone II (≤100% of the notified chemical) serves two functions. It will be dispersed within the drilling fluid system to increase viscosity and control the density of the mud-slurry at a concentration of less than 3% (<3% notified chemical). It will also be used in conjunction with Quik-Free in the event of a blocked pipe.

After the well treatment, the drilling mud, containing the notified chemical will either be re-used (reprocessed on shore), disposed in accordance with local requirements, or re-injected into the well-hole formation.

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)*
Mud Engineer[a]	0.5	1
Drill Rig Contractor[a]	0.5	1
Drill Rig Contractor[b]	0.25	183

(a) For the product Quik-Free
(b) For the product Geltone II

EXPOSURE DETAILS
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.

Dermal and ocular exposure to the notified chemical at up to 100% concentration may occur during mixing and connecting pump lines, and during maintenance and cleaning of equipment. Exposure is expected to be limited by the stated use of personal protective equipment (PPE) including impervious gloves, protective clothing and goggles or a face shield.

The product Geltone II (contains 60-100% notified chemical) is in powder form and workers handling the product may experience inhalation exposure, particularly during transfer operations. Geltone II is used more frequently than Quik-Free however a relatively short time of handling is expected. The well sites where the products are handled are situated in open air.

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

No toxicity data were submitted by the notifier. An OECD SIDS Initial Assessment Report (SIAR) is available for the organoclay chemical category, which is considered appropriate to the notified chemical. The SIAR and associated dossiers provide the following findings:

Toxicokinetics, metabolism and distribution.

Absorption, distribution and excretion of a chemical from the organoclay group has been investigated in the rat by single oral (gavage) exposure. Direct and rapid excretion in the faeces and negligible elimination through urine and bile were observed. There was also no evidence of tissue retention or systemic uptake of the chemical. Based on the results, absorption of the notified chemical is not expected following oral (gavage) exposure.

No particle size distribution study on the notified chemical was provided. However the OECD report states that based on physico-chemical properties and the reported particle size distribution data for consumer and industrial products in the chemical category, they are not expected to be respirable and not expected to be absorbed through the skin. However the OECD report further states that nano-sized particles may be included in the particle size distributions of this chemical category, however the studies available to the OECD report did not address the toxicity of nano-sized materials.

Acute toxicity.

An acute inhalation study similar to OECD TG 403 using five rats per sex exposed to a dust aerosol of a chemical from the organoclay category by whole body inhalation at a concentration of 5.2 mg/L for four hours gave an LC50 of > 5.2 mg/L. There were no unscheduled deaths. Adverse effects included decreased levels of activity, nasal discharge, respiratory irregularity and decreased group mean body weight, none of which persisted until sacrifice. There were no treatment related abnormalities during necropsy.

Two acute oral (gavage) studies similar to OECD TG 401 on a chemical from the group using five rats per sex provided an LD50 of > 5000 mg/kg bw. Both studies reported no unscheduled deaths. Clinical signs in both studies included diarrhoea in two males (study 1) and one female (study 2).

Irritation and sensitisation.

Several irritation studies were carried out on a chemical from the organoclay group. Two skin irritation studies using rabbits conducted on the chemical at 50% showed no reactions on any animal in either study. Human studies using the chemical at 10% applied to the backs of each of the 50 subjects showed irritation in four subjects in one study and three subjects in the second study. The level of irritation was slight in some subjects, and showed clear erythema in some subjects. In both studies the chemical was considered by the study authors to be well tolerated by the skin.

An eye irritation study on the same organoclay chemical was conducted using nine rabbits (0.1 mL test substance, no vehicle was reported). Six of the rabbits had treated eyes unwashed; the other three, washed four seconds after instillation onto one eye. Using the Draize scale, the test substance was considered moderately irritating to eyes without wash-out and non-irritating to eyes with wash-out.

Two separate human studies using 10 human volunteers per study was conducted on the same chemical using 2 mg of undiluted powder (first study) and 0.1 mL suspension of 200 g test substance in 100 mL corn oil or saline (second study) inserted into the conjunctival sac of one eye and observed up to 24 hours post-exposure. In both studies, none of the subjects reported pain or stinging. All subjects in study 1 and those that received saline suspension in study 2 reported a sensation of sand or gravel on the eye. Study 2 reported that no visible damage to the eyes was detected during the observation period.

Skin sensitisation studies carried out on several chemicals from the organoclay group indicate that these chemicals are not sensitisers. In one study (OECD TG 406) , guinea pigs were induced intradermally (as first induction using 0.5% w/w test substance in liquid paraffin) and topically (as second induction using 30% w/w test substance in liquid paraffin). The topical challenge involved using 30% and 15% w/w test substance in liquid paraffin. No dermal reactions were observed.

Repeated dose toxicity.
No repeated dose dermal or inhalation studies were available for the organoclay group. As the organoclay particles include sizes that are respirable (< 10µm) the OECD reports that effects on the lungs may be of concern if respirable organoclay particles are inhaled in sufficient doses.

Repeated dose toxicity studies by the oral route (gavage or dietary) have been carried out on several organoclays. In a 28-day repeated dose oral (gavage) study in rats similar to OECD TG 407, five animals per sex per group were treated with the notified chemical at 0 and 1000 mg/kg bw/day. No mortalities or signs of substance-related toxic effects were observed. No statistically significant effects were reported. The NOAEL was > 1000 mg/kg bw/day.

Mutagenicity/Genotoxicity.
Several chemicals from the organoclay group were non mutagenic in bacterial reverse mutation assays, with and without metabolic activation. One chemical was also tested in an *in vitro* mammalian gene cell mutation study, with negative results.

No evidence of chromosome damage was detected in *in vivo* genotoxicity studies on members of the organoclay group. Positive controls were not used, and the vehicle controls gave the appropriate response. Changes in the ratio of polychromatic to normochromatic erythrocytes were not seen. The OECD report states that further testing is not appropriate because of the physico-chemical properties of the chemicals.

Toxicity for reproduction.
A one-generation reproductive/developmental toxicity study (OECD TG 415) was conducted with an organoclay chemical using 24 rats/sex dosed orally (gavage) at levels of 0, 50, 225 and 1000 mg/kg bw/day. Males were dosed daily for 74 days prior to and during mating and females for 18 days prior to mating, through mating and during gestation and through to lactation day 21. There were no treatment-related effects on adults and offspring at any dose level. A NOAEL of 1000 mg/kg bw/day was established for both parental and F1 toxicity.

Impurities
The notified chemical contains up to 5% quartz as an impurity. Crystalline silica in the form of quartz or cristobalite dust causes cancer of the lung (IARC, 2012). A recent Canadian evaluation of quartz and cristabolite considered that adequate data exists for a threshold approach to risk characterisation. It also reported that numerous epidemiological studies have identified a positive correlation between workplace exposure to crystalline silica and increased risks of lung cancer however there is little evidence that low-level exposure to silica causes adverse health effects in man. Aggressive engineering controls to reduce silica dust in the workplace have shown to reduce silicosis (Environment and Health Canada, 2013). IARC (2012) notes that effects after long residency in the lung have not been systematically assessed.

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on studies on the organoclay group of chemicals, the notified chemical may be moderately irritating to the eyes. It is of high molecular weight and insoluble in water, properties that may lead to lung overloading. The particle size is not known, and if respirable or nano-sized particles are present, adverse lung effects may occur. The chemical also contains crystalline silica as an impurity, a material that has been associated with carcinogenic effects following inhalation exposure.

There is a potential for substantial dermal, oral, ocular and inhalation exposure of workers to the notified chemical at up to 100% concentration, during handling of Geltone II in powder form. Less exposure to the notified chemical in Quik-Free is expected, as it is present at <5% and is not in powder form. The greatest concern for the health of workers relates to inhalation.

An uncertainty is the lack of information on particle size, as no study has been carried out. Even though the notifier states that there are no intentionally produced nano-sized particles in the notified chemical, the OECD SIAR for the organoclay category mentions that nano-sized particles may be present. The toxicity of nano-sized particles alone is not discussed in the OECD report.

The risk to workers would be reduced by workplace controls to reduce exposure. Provided that control measures are in place to minimise worker exposure to the notified chemical, including the use of PPE (particularly eye and respiratory protection), safe work practices to reduce generation of dust/aerosols and well ventilated environments, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

The public is not expected to be exposed to the notified chemical except in an event of an accident during road transport; hence the risk to the public is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as finished end-use products for use in on-shore and off-shore drilling and will not be reformulated in Australia. Therefore, no environmental release is expected from manufacturing or reformulation in Australia. The release of the notified chemical to the environment during import, storage, and transport is also unlikely. Release from residues in storage and shipping containers is expected to be minimal. Spills or accidental release of the products are expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical in Quik-Free will be used as part of a specific treatment application to free stuck pipes during the drilling of some oil and gas wells. Quik-Free is typically mixed with barite (to increase density) in a hopper, after which the mixture is pumped down-hole for on- and off-shore operations.

The notified chemical in Geltone II will be used for specific treatment application by incorporating the product in the bulk drilling fluid to increase viscosity and impart suspension properties to oil-based drilling fluids and synthetic-based mud systems. Geltone II will also be used in oil-based drilling agents and fluids to change the mud-slurry density, to help control settling and thickening.

After the product (Geltone II or Quik-Free) has been placed down-hole, the mixture containing the notified chemical will remain in the well during drilling operations as part of the active fluid system. Once drilling activities at the well are completed, the drilling mud can either be pumped out of the well-hole or disposed of according to local regulations, recycled, or re-used (reprocessed on-shore).

RELEASE OF CHEMICAL FROM DISPOSAL

Oil-based or synthetic muds:

Both products can be used in oil-based or synthetic mud systems. Disposal of synthetic drilling fluid (*i.e.*, "mud") is rare due to the high value of the fluid and the significant disposal costs. All reasonable means may be taken to economically retain and reuse the fluids.

If the mud cannot be re-used, it will be sent to a registered disposal facility. The solids containing most of the notified chemical may be end up in landfill or a tailing dam. Furthermore, solids which have been generated through mechanical separation to recondition the fluid would also be most likely sent to landfill.

Water-based muds:

Only Quik-Free can be used in water-based muds. After the completion of drilling operations, the drilling mud containing the notified chemical is expected to be pumped out for disposal, recycling or reuse.

For off-shore operations, the drilling mud may be released directly to the ocean on a batch-wise basis, which is the worst case scenario. For on-shore operations, if the drilling mud cannot be re-used, it may be sent to a tailing dam for evaporation before being disposed of at a registered facility. Solids (containing most of the notified chemical) generated from drilling fluid reconditioning are expected to be sent to landfill.

The original containers are expected to be disposed of to landfill.

7.1.2. Environmental Fate

The notified chemical is not expected to biodegrade rapidly based on to the provided study. This may be due to a significant proportion of inorganic components in the notified chemical. For the details of the environmental fate studies please refer to Appendix B. Based on its high molecular weight and limited bioavailability, the notified chemical is not expected to bioaccumulate.

In most circumstances, the notified chemical will be incorporated into the bulk drilling fluid and share the fate of the drilling mud. The mud systems will be pumped out of the wells for disposal, recycling or reuse after the completion of drilling operations. Oil-based drilling mud is expected to be re-used and is not expected to be directly released to the water environment. For off-shore application, the water-based mud solids may be disposed of to the ocean after use. For on-shore application, the mud solids are expected to be most likely sent to landfill or a tailing dam.

In landfill or a tailing dam, the notified chemical is not expected to mobile based on its very high molecular weight and low water solubility. In the ocean, the notified chemical is expected to settle down to the sediment. In all the cases, the notified chemical is expected to ultimately degrade via biotic or abiotic pathways to form water and oxides of carbon, nitrogen and inorganic matter.

7.1.3. Predicted Environmental Concentration (PEC)

Off-shore application

Quik-Free – $PEC_{water,batch:}$

As direct discharge of the notified chemical into seawater is likely from off-shore use, the Predicted Environmental Concentration in seawater (PEC_{water}) has been calculated based on the CHARM model (Thatcher et al., 2005). Given that batchwise discharges are preferred, the conservative PEC water associated with batchwise discharges has been calculated as follows:

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

where: $PEC_{water, batch} = PEC_{water}$ for batchwise discharges

M = Mass of product discharged; upper range used as worst-case scenario;

V_m = 375 m^3 (volume mud discharged from a specific section; default value from Thatcher *et al*. 2005; p. 46); and

D_{batch} = 7.7 x 10^{-5} (batchwise discharge dilution factor; default value from Thatcher *et al*. 2005; p. 69).

The above equation represents the $PEC_{water,batch}$ for Quik-Free in water-based muds during batchwise discharges. The calculated $PEC_{water,batch}$ for Quik-Free in water-based muds during batchwise discharges is < 0.1 mg/L. The details for this calculation, including the data used, are present in a separate exempt information report.

Quik-Free – $PEC_{sediment:}$

To calculate a PEC in sediment ($PEC_{sediment}$) for the notified chemical, the CHARM model uses the PEC in water under a continuous discharge model ($PEC_{water, cont.}$) and the sediment-water partitioning behaviour of the notified chemical. The PEC in water for batchwise discharges is not used for this partitioning, since it is only present for

a short period of time, while the partitioning calculations assume an equilibrium situation. The $PEC_{sediment}$ for the notified chemical in Quik-Free was calculated using the following equation (Thatcher *et al*. 2005; p 30):

$$PEC_{sediment} = PEC_{water,cont} \times P_{sw} \times (1 - d_{s365})$$

where: $PEC_{sediment}$ = PEC in sediment around the platform (mg/kg);

$PEC_{water,cont}$ = PEC in water under a continuous discharge model;

P_{sw} = sediment-water partition coefficient (L/kg);

d_{s365} = fraction of chemical degraded in sediment in one year;

The calculated $PEC_{sediment}$ for the notified chemical in Quik-Free is < 2.0 x 10^{-6} mg/kg. The details for this calculation, including the data used, are present in a separate exempt information report. <u>*On-shore application*</u>

Based on the information provided by the notifier, significant release of the notified chemical to the aquatic environment from on-shore use is not expected. Therefore, the calculation of PEC for on-shore application is not necessary.

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*
Marine Fish Toxicity	96 h LC50 > 1000 mg/L (WAF)	Not harmful
Marine Copepod Toxicity	48 h EC50 > 2000 mg/L (WAF)	Not harmful
Marine Algal Toxicity	72 h EC50 > 1000 mg/L (WAF)	Not harmful
Marine Sediment Re-worker Toxicity	10 d LC50 > 10,000 mg/kg soil	Not harmful

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.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) for the notified chemical in water phase has been calculated and is presented in the table below. The PNEC is calculated based on the lower limits of the endpoints for the notified chemical (fish 96 h LC50 > 1000 mg/L or alga 48 h EC50 > 1000 mg/L) and an assessment factor of 100. An assessment factor of 100 has been used as acute toxicity endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50/EC50 (fish or alga)	> 1000	mg/L
Assessment Factor	100	
PNEC:	> 10	mg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC mg/L	PNEC mg/L	Q
Q - Ocean	< 0.1	> 10	**< 0.01**

The risk quotient (Q = PEC/PNEC) for the ocean environment is calculated to be < 0.01 for the water column.

For the ocean sediment organisms, the $PEC_{sediment}$/LC50 for sediment re-worker can be calculated as <2.0 x 10^{-6} mg/kg/10^{4} mg/kg = 2.0 x 10^{-10}.

Both ratios suggest that the notified chemical is not expected to have a potential concern to aquatic organisms. Based on its low water solubility and high molecular weight, the notified chemical is not expected to bioaccumulate in aquatic organisms.

On the basis of PEC/PNEC ratio and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the aquatic environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient (n-octanol/water) log Pow = -0.1548 at 20 °C

Method	Solubility of the notified chemical in water and 1-octanol were determined for the determination of Partition Coefficient.
Remarks	The water solubility was determined to be 0.34% (w/v) and the solubility in 1-octanol was determined to be 0.24 % (w/v). Therefore, the log Pow was calculated as -0.1548. This value may not be accurate since the notified chemical has low solubilities in both water and 1-octanol.
Test Facility	Halliburton Baroid (2004)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	Marine BODIS – ISO/TC 147/SC 5/WG 4N 141
Inoculum	Natural seawater
Exposure Period	42 days
Auxiliary Solvent	Not applied
Analytical Monitoring	Biological oxygen demand (BOD) determination
Remarks - Method	The test was conducted according to the guideline above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The test was established in three replicates in the following groups: oxygen consumption blank control, support medium control, reference sodium benzoate control, reference oil (olefin oil) control, test substance, and test substance with sodium benzoate. The test bottles were re-measured at each test point then re-aerated immediately to saturation before resealing and incubating at 20°C with continuous agitation.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	5	7	75
28	10	28	81
42	11	42	79

Remarks - Results	All validity criteria for the test were satisfied. Up to 44% of degradation was achieved with the toxicity control (test substance with sodium benzoate). The reference oil control achieved 31% of degradation by day 28 and 36% by day 42. The notified chemical is not considered to biodegrade rapidly based on the test outcome. However, it is noted that high degree of biodegradation may not be possible due to the presence of a significant proportion of inorganic substance in the notified chemical.
CONCLUSION	The notified chemical is not rapidly biodegradable
TEST FACILITY	Opus (2005)

B.2. Ecotoxicological Investigations

B.2.1. Acute toxicity to marine fish

TEST SUBSTANCE	Notified chemical
METHOD	Semi-Static Acute Toxicity Test Following Paris Commission (PARCOM) Method (1995) and OECD TG 203 Guidelines
Species	Juvenile Turbot (*Scophthalmus maximus*)
Exposure Period	96 hours
Auxiliary Solvent	Not applied
Salinity	32.2 ‰
Analytical Monitoring	Not applied
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, the supernatant was siphoned and used as treatment solution.

RESULTS

Concentration mg/L Nominal	*Number of Fish*	*Mortality (cumulative)*				
		1 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0	0
100.0	7	0	0	0	0	0
177.8	7	0	0	0	0	0
316.2	7	0	0	0	0	0
562.3	7	0	0	1	1	1
1000	7	0	0	0	0	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. The notified chemical is considered not harmful to fish since no significant effects were observed up to the top test level of 1000 mg/L (WAF).

CONCLUSION The notified chemical is not harmful to fish

TEST FACILITY STL (2004)

B.2.2. Acute toxicity to marine copepod

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	Not applied
Salinity	34.8 ‰
Analytical Monitoring	Not applied
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 filtered seawater. After a spinning and settling period, the test substance settled at the bottom of each vessel, leaving the water column clear. The clear solution was used as treatment solution.

RESULTS

Concentration mg/L Nominal	*Number of A. tonsa*	*% Immobilised 48 h*
Control	30	13
200	20	15
355.7	20	25
632.5	20	30

1124.6	20	30
2000.0	20	40

LC50	> 2000 mg/L at 48 hours (WAF)
NOEL	200 mg/L at 48 hours (WAF)
Remarks - Results	There was no evidence of a dose response in this study. Probit analysis was used to calculate the endpoints. It was noticed that the percent mortality of the test organisms in control exceeded 10%. Therefore, a validity criterion of the test was not satisfied. For this reason, the test may not be fully reliable.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates
TEST FACILITY	HE (1998a)

B.2.3. Acute toxicity to sediment re-worker amphipod

TEST SUBSTANCE	Notified chemical
METHOD	Semi-Static Acute Toxicity Test Following Paris Commission (PARCOM) Method (1995)
Species	Sediment re-worker amphipod (*Corophium volutator*)
Exposure Period	10 days
Auxiliary Solvent	Not applied
Salinity	32.6 ‰
Analytical Monitoring	Not applied
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

Concentration mg/kg dry soil Nominal	*Number of C. volutator*	*% Mortality 48 h*
Control	100	10
1,000	60	41
1778	60	56
3162	60	51
5623	60	41
10,000	60	38

LC50	> 10,000 mg/L (10 day)
NOEL	Not established
Remarks - Results	All validity criteria for the test were satisfied. Above 50% mortality was observed at test levels of 1778 and 3162 mg/kg dry soil. However, the two higher concentrations of tests produced mortality less than 50%. Therefore, the LC50 was determined to be > 10, 000 mg/kg dry soil. The NOEC was not established.
CONCLUSION	The notified chemical is not harmful to the sediment re-worker amphipod
TEST FACILITY	HE (1998b)

B.2.4. 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)*
>1000	*Not established*

Remarks - Results	All validity criteria for the test were satisfied.
CONCLUSION	The notified chemical is not harmful to algae
TEST FACILITY	HE (1998c)

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