File No: LTD/1640

August 2014

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.

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

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1640	Halliburton Australia Pty Ltd	Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine	Yes	< 1 tonne per annum	Additive for oil and gas drilling

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System for the 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

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

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:
  - Use of 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
  - Clean up spills and splashes promptly

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced in the product:
  - Impervious gloves
  - Protective clothing
  - Chemical goggles
  - Face shields (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 for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical;
  - 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 “stuck pipe” additive for oil and gas drilling, or is likely to change significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Halliburton Australia Pty Ltd (ABN: 73 009 000 775)
Level 10, 12-14 The Esplanade
PERTH WA 6000

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
US, Canada, China, EU, Korea, New Zealand, Philippines, Turkey.

2. IDENTITY OF CHEMICAL

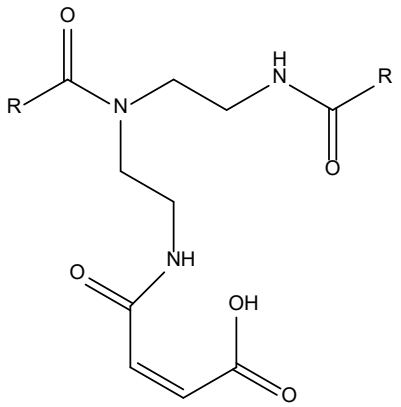
CHEMICAL NAME
Fatty acids, tall-oil, reaction products with diethylenetriamine, maleic anhydride, tetraethylenepentamine and triethylenetetramine

MARKETING NAME(S)
EZ SPOT (contains the notified chemical at ≤ 30% concentration)

CAS NUMBER
68990-47-6

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA
A representative structure for the major component of the notified chemical is depicted below:



R = alkyl chain from tall oil fatty acid

MOLECULAR WEIGHT
> 500 Da (major component)

3. COMPOSITION

DEGREE OF PURITY > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: brown green semi-solid (for the product EZ SPOT)

Property	Value	Data Source/Justification
Freezing Point	-10 °C	(M)SDS for the product EZ SPOT
Boiling Point	Not determined	-
Density	977 kg/m^3 at 20 °C	(M)SDS for the product EZ SPOT
Vapour Pressure	Not determined	-
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	33 °C	(M)SDS for the product EZ SPOT
Flammability	Not determined	Product is expected to be flammable based on flash point due to solvents.
Autoignition Temperature	Not determined	-
Explosive Properties	Not expected to be explosive	Does not contain functional groups that would imply explosive properties
Oxidising Properties	Not expected to be oxidising	Does not contain functional groups that would imply oxidative 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. The notified chemical should be stored away from strong oxidising agents.

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 a solvent based product (EZ SPOT) at ≤ 30% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.5	< 0.5	< 0.5	< 0.5	< 0.5

PORT OF ENTRY
Adelaide, Melbourne, Perth, Brisbane, and Darwin.

TRANSPORTATION AND PACKAGING
The product (EZ SPOT) containing the notified chemical at ≤ 30% concentration will be imported into Australia in 15 gallon (~56 L) and 55 gallon (~208 L) drums. These drums will be transported by truck to onshore drilling sites, and by ship to offshore drilling sites.

USE
The notified chemical is a component of EZ SPOT, a product used to free up blocked drilling pipes incurred during drilling for oil and gas wells, both onshore and offshore. The product breaks up the filter cake that causes these pipes to become blocked.

OPERATION DESCRIPTION
At the drilling sites, the product containing the notified chemical at ≤ 30% concentration will be mixed with other components (base oil, water and other products) and pumped into position in the well bore which has a blocked or stuck pipe. The notified chemical will comprise < 3% of this mixture. Once the blockage has cleared and the product circulates throughout the drilling fluid, the resulting final concentration of the notified chemical in the drilling fluid will generally amount to less than 0.3%.

Although the incidence of blocked or stuck drilling pipes is variable and occurs in less than 1% of drilled wells, the product containing the notified chemical will be regularly available at the drilling site in readiness for this occurrence. Once well drilling is complete, the drilling fluid containing the notified chemical may be either re-used (if it is synthetic or oil based) or, if it is water-based, disposed of in accordance with local requirements.

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)*
Laboratory Technicians	0.5	6
Mud Engineer/Technician	2	6

EXPOSURE DETAILS
Exposure of workers to the notified chemical at up to 30% 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 ≤ 30% concentration may occur when mixing the product 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.

Once the well drilling is completed, workers may be exposed to the drilling fluid containing < 0.3% 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

No toxicity data were submitted.

The notified chemical is a reaction mixture and will have several components of varying molecular weight. Based on the molecular weight of <1000 Da, and the partition coefficient (log Pow = 3.19), dermal absorption of the notified chemical is possible. It has structural alerts for skin sensitisation, and such effects from the notified chemical may occur. Furthermore, based on structural considerations, the potential for the notified chemical to cause skin and eye irritation cannot be ruled out.

The notifier has classified the product containing the notified chemical as a skin sensitiser and serious eye irritant.

Health hazard classification
As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The possibility of eye and skin irritation and skin sensitisation cannot be discounted. Therefore workers at the end-use sites may be at of risk of these effects through dermal and ocular exposure to the notified chemical at up to 30%. The risk would be mitigated by the use of personal protective equipment (PPE) including gloves, protective clothing and goggles or a face shield.

The risk to workers from exposure to the drilling fluid containing < 0.3% notified chemical when drilling is completed would be reduced, due to the low concentration.

Therefore the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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 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. During use the notified chemical is incorporated into the drilling mud mixture, with a final concentration of < 0.3%.

EZ SPOT will be utilized in a low percentage of wells regardless of mud system.

The notifier indicates that the used water-based drilling mud will be disposed of in accordance with local requirements.

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, muds are expected to be sent to a registered disposal facility, which is most likely 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. 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, most 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 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:

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

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 specific values for volume of mud discharged and the dilution factor have 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 values, and the worst case discharge of the notified chemical in a single batch of used mud, the $PEC_{water,batch}$ for the notified chemical is calculated to be < 0.2 mg/L. The details for this calculation, including the data used, are present in a separate exempt information report.

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 is deposited in this layer of sediment, then the $PEC_{sediment}$ for the notified chemical in the benthic system is estimated to be <5 mg/kg. The details for this calculation, including the data used, are present in a separate exempt information report.

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 Toxicity	96 h LL50 > 1000 mg/L (WAF)	Not harmful
Daphnia Toxicity	48 h EL50 > 2000 mg/L (WAF)	Not harmful
Algal Toxicity	72 h E_rL50 = 23.8 mg/L (WAF) NOEL = 10 mg/L (WAF)	Harmful

The notified chemical is considered to be harmful to aquatic organisms based on the 72 h endpoint to alga. The 72 h NOEL for alga is 10 mg/L. 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 predicted no-effect concentration (PNEC) has been calculated using the endpoint for the most sensitive trophic level [alga 72 h E_rL50 = 23.8 mg/L] and an assessment factor of 100 as endpoints for all three trophic levels are available.

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:	< 0.2 mg/L	0.238	< 0.84

It is noted that this calculation is based on the conservative assumption that the total amount of the notified chemical used for an off-shore application is disposed of to the ocean. No removal to the sediment or via biodegradation has been considered. Therefore, the actual Q value is expected to be lower.

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

Partition Coefficient (n-octanol/water) log Pow = 3.19

Method OECD TG 117 Partition Coefficient (n-octanol/water).

Remarks HPLC method. No details of the test were provided. Based on the summary provided, two peaks were resolved with log P_{OW} of 1.65 (25%) and 3.7 (75%). The average log P_{OW} was calculated to be 3.19.

Test Facility IOE Group (1996)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.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)

B.2. Ecotoxicological Investigations

B.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)

B.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 (2003)

B.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)

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