File No: STD/1357

July 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Radiagreen EBL

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, 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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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

FULL PUBLIC REPORT

Chemical in Radiagreen EBL

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Robert Wee & Associates Pty Ltd (ABN 71 899 891 347)
6 Taylor Ave
LOCKLEYS SA 5032

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 name(s), CAS number, Molecular formula, Structural formula, Molecular Weight, Spectral Data, Methods of Detection and Determination, Degree of purity, Hazardous impurities, Non-hazardous impurities, Additives/adjuvants, Import volume, Details of Use, Identity of Sites

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a function of pH, Acute Inhalation Toxicity, Dissociation constant, Induction of Germ Cell Damage

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US, Canada, EU, China

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Marketing names of the imported formulation (containing 75% of the notified chemical):
Radiagreen EBL
Finagreen EBL
7857

ANALYTICAL DATA
Reference UV/VIS, IR and ^{1}H NMR spectra were provided by the notifier.

3. COMPOSITION

DEGREE OF PURITY >95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light-brown liquid with slight odour

Property	Value	Data Source/Justification
Boiling Point	Not determined	Decomposes at >325 °C
Density	974 kg/m^3 at 20°C	Measured
Vapour Pressure	< 1.47 x 10^{-6} kPa at 20°C	Measured
Water Solubility	< 1 x 10^{-3} g/L at pH 8, 20°C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains groups which are susceptible to hydrolysis. However hydrolysis is expected to be slow in the environmental pH range of 4-9.
Partition Coefficient (n-octanol/water)	log P_{OW} > 6.5	Estimated. A high P_{ow} is expected based on the mainly hydrophobic structure of the notified chemical.
Adsorption/Desorption	log K_{OC} > 5.63	Estimated. A high K_{OC} is expected based on the mainly hydrophobic structure.
Dissociation Constant	Not determined	The notified chemical does not contain any dissociable functional groups at environmental pH.
Particle Size	Not determined	Notified chemical is a liquid
Flash Point	200°C at 101.3 kPa	Measured
Flammability	Not expected to be flammable	Based on the flash point
Autoignition Temperature	395°C	Measured
Explosive Properties	Not expected to be explosive	Estimated 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 environmental conditions.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified chemical is not classified as dangerous according to the Australian Dangerous Goods Code (NTC, 2007). However the data above does not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia, but will be imported in a formulation (containing 75% of the notified chemical) from the EU.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<300	<300	<300	<300	<300

PORT OF ENTRY
Melbourne and Perth

TRANSPORTATION AND PACKAGING
The formulation containing the notified chemical will be imported by sea in 234 L drums.

USE

The notified chemical will be used as a drilling fluid additive in the oil and gas industry.

OPERATION DESCRIPTION
The notified chemical will be imported in a formulation at 75% concentration and transported to onshore and offshore oil drilling sites. At these sites the formulation will be unloaded and manually transferred into the drilling fluid at a concentration of approximately 1.2 – 1.85%. The drilling fluid will be pumped via a mostly enclosed system to mud pits and then down the well to the drill bit for drilling. The drill cuttings will return to the surface where the rock will be filtered out by shale shakers and the mud which contains the notified chemical (1.2 – 1.85%) will be returned to mud pits before being pumped back down the well for further use.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS
The number of workers expected to be exposed to the notified chemical is likely to be 2-3 at each site plus several transport workers.

EXPOSURE DETAILS
Transport workers are not likely to be exposed to the notified chemical except in the case of an accident involving damage to the import containers.

Workers handling the imported formulation containing the notified chemical at 75% concentration may encounter dermal and possibly ocular exposure during addition of the formulation to the drilling fluid. Dermal exposure is the most likely route and may occur during connection and disconnection of pipes. However, once the fluid containing the notified chemical has been added to the drilling fluid at approximately 1.2 – 1.85% concentration, the system is mostly enclosed and automated and exposure would not be anticipated. Workers may encounter exposure to the drilling fluid containing the notified chemical at 1.2 – 1.85% during changing the drill bit, or to the mud containing the notified chemical at 1.2 – 1.85% during transfer to shale shakers and separation tanks. Workers involved in these processes on drilling and processing sites are expected to wear personal protective equipment (PPE) such as safety helmets, safety glasses, coveralls and gloves to minimise dermal and ocular exposure.

Inhalation exposure to the notified chemical is also possible during addition of the imported formulation to the drilling fluid. However, due to its low vapour pressure ($<1.47 \times 10^{-6}$ kPa) and the enclosed systems used to transport the drilling fluids the notified chemical is not expected to be available for inhalation in significant quantities unless aerosols are generated during the processes.

6.1.2. Public exposure
The notified chemical is intended for industrial use on specific sites and therefore public exposure is not anticipated.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >5000 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
Mouse, skin sensitisation – Local lymph node assay	skin sensitiser
Rat, repeat dose oral toxicity – 28 days.	NOAEL >1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosomal aberration test (cultured peripheral human lymphocytes)	non genotoxic

Toxicokinetics
The notified chemical is of varying molecular weight but contains species with molecular weight <500 Da. It has low water solubility (<1 mg/L) and an estimated high log Pow (>6.5). Based on these properties, oral absorption may occur given the lipophilicity (log Pow >6.5) that would favour micellular solubilisation. There was no clear evidence of oral absorption in either the acute or repeat dose oral toxicity studies. If oral absorption were to occur, the notified chemical would be expected to undergo hydrolysis and then conjugated and readily excreted (NOTOX B.V., 2008g).

Dermal absorption is not expected to be favoured by the low water solubility (<1 mg/L) and high log Pow (>6.5). However, the lymphocyte proliferative response in the skin sensitisation study indicates that some dermal absorption has occurred.

The low vapour pressure of $<1.47 \times 10^{-3}$ Pa indicates that the availability of the notified chemical for inhalation will be limited. However, once present in the respiratory tract, the low water solubility (<1 mg/L) indicates a potential for accumulation, while its lipophilicity (log Pow >6.5) indicates the potential for absorption directly across the respiratory tract epithelium (NOTOX B.V., 2008g).

Acute toxicity.
The notified chemical was found to be of low acute oral toxicity in rats according to OECD TG 423 Acute Toxic Class Method. There were no mortalities or adverse findings reported in the study and the oral LD50 was estimated to be >5000 mg/kg bw.

The notified chemical was also found to be of low acute dermal toxicity (LD50 >2000 mg/kg bw) in rats according to OECD TG 402.

No acute inhalation toxicity study was provided. The notified chemical is a liquid with a low vapour pressure ($<1.47 \times 10^{-6}$ kPa) which suggests it will not be readily vaporise.

Irritation and Sensitisation.
The notified chemical was tested in rabbits for skin irritation and found to cause slight oedema and erythema which resolved within 3 days. It was concluded that the notified chemical was slightly irritating to skin but the effects were not sufficient for classification as a skin irritant according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008 (2004)].

The notified chemical was found to be slightly irritating to the eyes of rabbits in an eye irritation test.

The notified chemical was tested for contact hypersensitivity in a Local Lymph Node Assay (LLNA) according to OECD TG 429. Slight erythema of the treated skin and slight enlargement of lymph nodes was noted in animals tested at 50 and 100% concentrations. The Stimulation Index (SI) at 25, 50 and 100% concentration was determined to be 1.4, 4.7 and 6.9 respectively. SI values above 3 are considered be indicative of skin sensitisers and thus the notified chemical was considered to be a skin sensitiser.

Repeated Dose Toxicity
In a 28-day repeat dose oral toxicity study on the notified chemical, minor changes were noted in clinical chemistry parameters such as higher creatinine and glucose levels in males treated with 1000 mg/kg bw/day and lower sodium levels in males treated with 450 mg/kg bw/day but no dose-response could be established and the values were within the normal limits for rats of that age and strain. At necropsy, isolated changes in various organs were observed but there was no dose response and therefore these findings were not considered to be of toxicological significance. The no observed adverse effect level (NOAEL) was determined to be >1000 mg/kg bw/day.

Mutagenicity
The notified chemical was found not to be mutagenic when tested at up to 3300 µg/plate in a bacterial reverse mutation test conducted in the presence and absence of metabolic activation in *Salmonella typhimurium* strains TA1535, TA1537, TA98 and TA100 and *Escherichia coli* strain WP2uvrA according to OECD TG 471.

Genotoxicity
The notified chemical was found not to be clastogenic in an *in vitro* chromosome aberration test conducted with

peripheral human lymphocytes in the presence and absence of metabolic activation.

Health hazard classification
Based on the lymphocyte proliferative response observed in the LLNA study, the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008 (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 main concern for workers using the notified chemical is skin sensitisation as demonstrated in the LLNA study (NOTOX B.V., 2008f). Workers connecting and disconnecting hoses to drums of the imported formulation containing the notified chemical at 75% concentration may encounter dermal and ocular exposure to spills and splashes. Dermal and ocular exposure is expected to be minimised by the use of PPE and thus, the risk is not considered unacceptable. The use of PPE would also minimise any risk of irritation to the eyes or skin.

The potential for respiratory sensitisation has not been determined. The notified chemical has a low vapour pressure ($<1.47 \times 10^{-6}$ kPa) which suggests that it would not be available for inhalation. However, the mechanical pumping and drilling operations may create aerosols of the notified chemical. The use of respiratory protection or exhaust ventilation would reduce the potential for inhalation exposure to the notified chemical.

Workers may also encounter exposure to the drilling fluid and drilling mud cuttings containing the notified chemical at 1.2 – 1.85% concentration during activities such as changing the drill bit and transfer of the mud for separation and processing. These workers are also expected to wear PPE to minimise exposure and therefore the risk is not expected to be unacceptable.

Overall, the risk of skin sensitisation, skin and eye irritation is not expected to be unacceptable provided that appropriate PPE is used. Measures to reduce inhalation exposure are recommended to reduce any potential risk.

6.3.2. Public health
The public are not likely to be exposed to the notified chemical as it will only be used at a limited number of industrial sites. Therefore the risk to public health is expected to be negligible.

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 from overseas as a component of a formulation for end-use in Australia and will not be reformulated in Australia. Therefore, no environmental release is expected from the manufacture or reformulation of the notified chemical in Australia. Release from residue in import drums will be minimal (3000 kg per annum assuming 1% loss) as the product is a liquid and residues are expected to be either disposed of to landfill with empty containers or treated properly in the drums recycling process. Accidental spills of the product are expected to be absorbed with inert absorbent material, swept up and placed into containers and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be used in drilling mud during on-shore and off-shore oil well drilling operations. We have assumed a common application scenario that up to 6000 kg of the notified chemical (2% of the import volume) will be added to drilling mud for each well that is drilled. During oil well drilling operations, drilling mud containing up to 1.85% of the notified chemical will be pumped down the drill shaft during drilling of deep wells. The drilling mud will eventually be pushed out of the well and transferred to the surface for solids processing. This involves a sifting step along with low speed centrifugation in order to remove the drill cuttings. The drilling mud containing the notified chemical will be recovered and then replenished with additional mud containing more notified chemical and then transferred back down into the well. The drill cuttings that represent about 5-10% (assuming a common standard application scenario) of the material transferred to the surface contain some adhered drilling mud. After separation, the drill cuttings will contain approximately 5% entrained drilling mud. This is consistent with the literature value of 15% for a worst case and 5% for modern practices (Oil & Gas Producers, 2003). Although it is possible for cuttings to be re-injected into the well or collected for on-shore disposal or re-use as general fill, it would appear that this is not generally practiced in Australia. Consequently, in the case of off-shore drilling, the cuttings (and the entrained mud) will be discharged into the ocean. Thus, 5% of the notified chemical that is used in drilling mud for each well (300 kg) will be released into the ocean with drill cuttings during drilling operations off-shore. In the case of on-shore drilling, this quantity of notified chemical will be discharged into lined service pits along with the drill cuttings for later treatment.

RELEASE OF CHEMICAL FROM DISPOSAL

After the completion of drilling operations off-shore, the used drilling mud along with the remaining notified chemical will be discharged into the ocean. For the purposes of assessment, it is assumed that all of the notified chemical that is not released with the drill cuttings (95% or 5700 kg per well) will be subsequently discharged along with the used mud. For on-shore sites, all of the notified chemical associated with drill cuttings and drilling mud will be discharged into the lined service pits. These may be treated in several different ways, including being allowed to dry by evaporation, being picked up by vacuum trucks and transferred to disposal well sites for discharge, or simply covered with top soil and remediated *in situ*.

7.1.2 Environmental fate

The notified chemical reached a biodegradation of 55% in freshwater and the formulation containing 75% of the notified chemical reached a degradation of 71% in seawater. Therefore, the notified chemical is likely to have potential for biodegradation in the marine environment.

Due to the high estimated log K_{OC} of > 5.63, the notified chemical is expected to adsorb strongly to solids. Hence, the notified chemical discharged into seawater in the vicinity of off-shore oil-production sites is expected to remain closely associated with the mineral components of the drilling mud and cuttings, which will deposit in piles of waste material on the ocean floor beneath the discharge point. There is potential for the notified chemical to bioaccumulate as indicated by the study provided by the notifier, which complies with its hydrophobicity and molecular weight range. However significant bioaccumulation of the notified chemical in pelagic or benthic biota is not expected due to its likely potential to biodegrade in the marine environment and to degrade by abiotic processes.

For the details of the environmental fate studies, refer to Appendix C.

The notified chemical will be disposed of to the ocean and deposit on the seabed for off-shore application. After on-shore applications, it is expected to be disposed of to well sites for discharge or buried by top soil and remediated *in situ*. For both applications, the notified chemical will be decomposed over time, via biotic or abiotic processes, forming water and oxides of carbon.

7.1.3 Predicted Environmental Concentration (PEC)

Considering the insolubility of the notified chemical in water and its high K_{OC} value, most of the chemical discharged from the off-shore drilling sites is expected to remain entrained in the solids and mud in the cuttings and deposited in the sediment. The amount of notified chemical dissolved in water is expected to be very low. Therefore, the PEC_{water} has not been calculated.

An estimate of the $PEC_{sediment}$ can be made in accordance with the CHARM model (Thatcher et al., 2005) 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 47 100 tonnes. If it is further assumed for a worst case that 100% of the discharged mass of notified chemical in a batch of used mud (5700 kg) is deposited in this layer of sediment, then the $PEC_{sediment}$ for the notified chemical in the benthic system is estimated to be 121 mg/kg.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Turbot Fish Toxicity, Acute	LL50 (96 h) > 1800 mg/L (WAF)	Not harmful up to the limit of solubility
Acartia tonsa Invertebrate Toxicity, Acute	EL50 (48 h) > 1000 mg/L (WAF)	Not harmful up to the limit of solubility
Skeletonema costatum Algal Toxicity, Acute	E_rL50 (72 h) > 1000 mg/L (WAF)	Not harmful up to the limit of solubility
Skeletonema costatum Algal Toxicity, Chronic	NOEL = 180 mg/L (WAF)	
Inhibition of Bacterial Respiration	IC50 (72 h) > 100 mg/L	Not harmful
Daphnia Toxicity, Chronic (reproduction)	NOEL (21 d) = 32 mg/L[a] (WAF)	Not harmful up to the limit of solubility

[a] Appears to be based on a physical effect and not a toxic effect.

The notified chemical is not harmful to the aquatic organisms up to its limit of water solubility.

7.2.1 Predicted No-Effect Concentration

A PNEC for the aquatic compartment has not been calculated since the notified chemical is not harmful up to the limit of its solubility in water based on the studies provided by the notifier. A PNEC for the sediment compartment has not been calculated due to the lack of toxicity data (studies or QSAR modelling data) for sediment dewlling organisms.

7.3. Environmental risk assessment

The notified chemical will be used as a drilling fluid additive in the oil and gas industry. The environmental exposure of the notified chemical is therefore concentrated in a few locations. The main route for exposure of the environment to the notified chemical is through the discharge of drill cuttings and used drilling muds overboard at off-shore drilling sites. Effectively, all notified chemical used on off-shore drilling operations is expected to be discharged to the ocean at the completion of drilling.

The risk quotient (RQ = PEC/PNEC) for the water column in the ocean has not been calculated since no significant amount of the notified chemical discharged to seawater is expected to be dissolved in the water column, and due to the absence of any significant acute toxicity effects to species from 3 marine trophic levels. No unacceptable risk to pelagic biota is expected from the notified chemical when it is discharged in mud and cuttings into the ocean.

However, the main concern for the effects of the notified chemical to the benthic organisms dwelling in the seabed sediment via bioaccumulation. Due to its insolubility, nearly all of the notified chemical is expected to remain associated with the insoluble minerals and other solids discharged overboard and deposit in sediments on the ocean floor beneath the discharge point following a single batch-wise discharge of used mud. The concentration of the notified chemical in the sediment is expected to produce concentrations of up to 121 mg/kg of this chemical in the top 5 cm of sediment in a worst case. No study for long term effects of the notified chemical to benthic organisms is available. Also QSAR models such as ECOSAR (US EPA, 2009) do not provide estimations for endpoints in the sediment compartment. However, the study for the chronic toxicity of the notified chemical to daphnids, aquatic invertebrates that dwell in the water column and on the surface of sediment, indicates that no adverse effects were observed when the invertebrates are exposed to this chemical for 21 days up to the limit of its solubility in water (i.e. at loading rate of 32 mg/L). Significant mortality was observed, however, at a loading rate of 100 mg/L. This effect is considered invalid since the high mortality at 100 mg/L was considered to be due to the physical effects of the suspended particles of notified chemical in the test medium rather than the chemical toxicity of the notified chemical. We also note the deposition of cuttings may result in physical smothering of benthic organisms regardless of the nature of the cuttings (p. 29, Oil and Gas Producers, 2003) which, in this case, would be more likely to have adverse effects than any potential chemical toxicity of the notified chemical. Hence, the notified chemical disseminated through the top layer of sediment beneath the discharge points of off-shore oil-drilling sites are not expected to have chronic chemical toxic effects on benthic organisms.

The chronic toxicity data, the notified chemical's low water solubility and its potential to biodegrade in seawater indicates bioaccumulation of the notified chemical in benthic organisms is not expected.

Based on the expected low concentration of the notified chemical in the water column, its low toxicity to aquatic life and its low expectancy to bioaccumulate, the notified chemical is not expected to have adverse toxic effects on either pelagic or benthic biota in the immediate vicinity of off-shore oil-drilling sites following a worst-case discharge of used drilling mud. The environmental risks associated with the introduction and intended use of the notified chemical are therefore acceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008 (2004)] with the following risk phrase:

R43 May cause sensitisation by skin contact

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Skin sensitisation	1	May cause an allergic reaction

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers provided that appropriate PPE are used.

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

Environmental risk assessment
Based on its reported use pattern, insolubility and lack of toxicity to marine biota, the notified chemical is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified chemical:

R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥1%: R43 May cause sensitisation by skin contact

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 allergies.

Material Safety Data Sheet

- The MSDS provided by the notifier should be amended as follows:
  - the notified chemical should be identified by its chemical name (as it is a Type 1 ingredient based on its skin sensitisation potential).

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced in the product Radiagreen EBL and when diluted for use:
  - Avoid skin and eye contact
  - Avoid generation of aerosols during addition to drilling fluids

- Employers 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 Radiagreen EBL and when diluted for use:
  - Impervious gloves
  - Coveralls

- Respiratory protection where inhalation exposure is possible or aerosols 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 MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must 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(2) of the Act; if
- the function or use of the chemical has changed from drilling fluid additive in the oil and gas industry, or is likely to change significantly;
- the amount of chemical being introduced has increased to more than 300 tonnes, 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 MSDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Tests were conducted on the notified chemical at >95% purity.

Boiling Point Decomposes > 325°C at 101.3 kPa

Method	OECD TG 103 Boiling Point. EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Determined by DSC
Test Facility	NOTOX B.V. (2007a)

Density 974 kg/m^3 at 20°C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined by pycnometer
Test Facility	NOTOX B.V. (2007a)

Vapour Pressure < 1.47 x 10^{-6} kPa at 20°C

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Isothermal thermogravimetric effusion method. The measurement of evaporation rates was conducted at temperatures < 240°C. The weight loss of the notified chemical at 100°C was significantly lower than that of a reference substance hexachlorobenzene (vapour pressure 1.47×10^{-6} kPa at 20°C).
Test Facility	NOTOX B.V. (2007a)

Water Solubility < 1 x 10^{-3} g/L at pH 8, 20°C

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	Flask Method. Following a preliminary test, 9.8 mg and 16.3 mg of the notified chemical were separately mixed with 250 mL of double distilled water and magnetically stirred at 20±0.6˚C for up to 72 hours. A blank control was also conducted. Duplicate samples were taken and analysed after further centrifugation, removal of the surface floating particles, and filtration by a 0.45µm membrane. The water solubility was determined to be less than the limit of quantification (LOQ = 1 × 10^{-3} g/L) at pH 8.0.
Test Facility	NOTOX B.V. (2007a)

Partition Coefficient (n-octanol/water) log P_{OW} > 6.5

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks	HPLC Method. The dead time was determined by using thiourea. The column temperature was set as 22±1˚C. The partition coefficient has been determined to be log P_{OW} > 6.5 since the retention time of the notified chemical was longer than that of 2,4-DDT.
Test Facility	NOTOX B.V. (2007a)

Adsorption/Desorption – screening test log K_{oc} > 5.63

Method	OECD TG 121 Estimation of the Adsorption Coefficient (K_{OC}) on Soil and on Sewage Sludge Using High Performance Liquid Chromatography (HPLC). EC Directive 2001/59EC. C.19 Estimation of the Adsorption Coefficient (K_{OC}) on Soil and on Sewage Sludge Using High Performance Liquid Chromatography (HPLC).
Remarks	HPLC method at neutral pH. The dead time was determined by using formamide. The

column temperature was set as 35˚C. The partition coefficient has been determined to be log K_{OC} > 5.63 since the retention time of the notified chemical was longer than that of 2,4-DDT.

Test Facility NOTOX B.V. (2007a)

Flash Point 200ºC at 101.3 kPa

Method EC Directive 92/69/EEC A.9 Flash Point.
Remarks Closed cup method
Test Facility NOTOX B.V. (2007a)

Autoignition Temperature 395ºC

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility NOTOX B.V. (2007a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (>95%)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar strain Crl:WI (SPF)
Vehicle	Notified chemical administered undiluted
Remarks - Method	No significant protocol deviations. The notified chemical was administered to two subsequent groups of three female rats at 2000 mg/kg bw.

RESULTS

LD50	>5000 mg/kg bw
Signs of Toxicity	No mortalities or signs of toxicity observed.
Effects in Organs	No abnormalities observed at necroscopy
Remarks - Results	Hunched posture noted in all animals on Day 1. All animals exhibited normal weight gain. The oral LD50 value of the notified chemical was established to >2000 mg/kg bw. However, based on these results and according to the OECD 423 test guideline for Acute Toxic Class Method, the LD50 cut-off value in this case was considered to be >5000 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	NOTOX B.V. (2008a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified chemical (>95%)
METHOD	OECD TG 402 Acute Dermal Toxicity.
Species/Strain	Rat/ Wistar strain Crl:WI (SPF)
Vehicle	None
Type of dressing	Occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 females	2000	0
2	5 males	2000	0

LD50	>2000 mg/kg bw. No mortalities were observed.
Signs of Toxicity - Local	Scales and/or maculate erythema were noted in 3 female animals, which were all cleared by Day 7.
Signs of Toxicity - Systemic	Piloerection or chromodacryorrhoea noted in majority of animals. All animals recovered from these symptoms between Day 2 and 3.
Effects in Organs	No abnormalities observed at necroscopy.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.
TEST FACILITY	NOTOX B.V. (2008b)

B.3. Irritation – skin

TEST SUBSTANCE Notified chemical (>95%)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 males
Vehicle None
Observation Period 72 hours
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations

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	0.67	0.67	0.67	2	48 hrs	0
Oedema	0.67	0	0.33	2	48 hrs	0

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

Remarks - Results Sticky and dry remnants of the notified chemical were observed on the skin of 1 rabbit on Day 1.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY NOTOX B.V. (2008c)

B.4. Irritation – eye

TEST SUBSTANCE Notified chemical (>95%)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 males
Observation Period 72 hours
Remarks - Method No significant protocol deviations. Fluoroscein evaluation of the eyes was carried out at 24 hours.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0.3	0.3	1	< 48 hrs	0
Conjunctiva: chemosis	0	0	0	1	< 24 hr	0
Conjunctiva: discharge	0	0	0	1	< 24 hr	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results Instillation of the notified chemical resulted in slight irritation of the conjunctivae, consisting of redness, chemosis and discharge. These effects had completely resolved in all animals by 48 hours.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY NOTOX B.V. (2008d)

B.5. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical (>95%)
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents. EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).
Species/Strain	Rat/Wistar Crl:(WI)BR (SPF)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week
Vehicle	None
Remarks - Method	No significant protocol deviations. No recovery groups were included.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	5 per sex	0	0
low dose	5 per sex	150	0
mid dose	5 per sex	450	0
high dose	5 per sex	1000	0

Mortality and Time to Death

No unscheduled deaths occurred over the course of the study.

Clinical Observations

No signs of clinical toxicity occurred during the course of the study. Alopecia and/or scabs were observed on the neck of one male at 1000 mg/kg bw/day and one female at 150 mg/kg bw/day but these findings are common in this type of study in rats and were not considered to be of toxicological significance.

No significant abnormalities were observed in the motor activity assessments.

A statistically significant lower body weight gain was noted in males treated at 150 and 450 mg/kg bw/day, however these changes were not considered to be of toxicological significance since the body weight gain of males in the 1000 mg/kg/day group was comparable to the control group.

Laboratory Findings – Clinical Chemistry, Haematology

Higher creatinine and glucose levels were observed in males treated with 1000 mg/kg bw/day and lower sodium levels were observed in males treated with 450 mg/kg bw/day but these values were still within accepted norms for this age and strain of rat and since no dose-response relationship could be established the findings were not considered to be toxicologically significant.

Effects in Organs

The following incidental findings were reported during macroscopic examination: pale discolouration of the lungs, dark red foci on the thymus, enlargement of the liver, gray-white foci on the papillary process of the liver, reduced size of testes and epididymides, reduced ovary size and scab formation on the skin. There was no dose-response relationship with the severity or incidence of these findings and therefore they were not considered to be toxicological significance.

No significant dose-related findings were reported during microscopic examination.

Remarks – Results

No treatment-related adverse effects were reported in the study.

CONCLUSION

The No Observed Adverse Effect Level (NOAEL) was established as >1000 mg/kg bw/day in this study.

TEST FACILITY NOTOX B.V. (2008e)

B.6. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical (>95%)
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, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Rat S9 fraction from phenobarbital/β-napthoflavone induced rat liver (5% in Test 1, 10% in Test 2)
Concentration Range in Main Test	a) With metabolic activation: 33-3330 µg/plate b) Without metabolic activation: 33-3330 µg/plate
Vehicle	Ethanol
Remarks - Method	No significant protocol deviations. In preliminary toxicity testing, precipitation was observed at dose levels of 3330 and 5000 µg/plate. Precipitation was initially observed at concentrations of 1000 and upwards and at 3330 µg/plate and at 5000 µg/plate at the end of the incubation period. Test 1 includes the results of the preliminary test, which was carried out to 5000 µg/plate on two strains and to 3000 µg/plate on the remaining three strains.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>3330	3330	negative
Test 2	Not performed	>3330	3330	negative
Present				
Test 1	>5000	>3330	3330	negative
Test 2	Not performed	>3330	3330	negative

Remarks - Results	Slight test material precipitate was observed on plates at 3330 µg/plate in the presence and absence of S9-mix. Precipitation was initially observed at concentrations of 1000 and 3330 µg/plate and at 3330 µg/plate at the end of the incubation period. No significant increase in the frequency of revertant colonies was recorded for any bacterial strain at any dose either with or without metabolic activation compared to the controls.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	NOTOX B.V. (2007b)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE	Notified chemical (>95%)
METHOD	OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
Cell Type/Cell Line	Cultured peripheral human lymphocytes
Metabolic Activation System	Rat liver S9-mix induced by a combination of phenobarbital and β-naphthoflavone
Vehicle	Ethanol
Remarks - Method	The assays were conducted with minor modifications as described by

Evans (1984). However, these modifications were not detailed in the study report. No other significant protocol deviations.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	10*, 33*, 100*	3 h	24 h
Test 2	10*, 33*, 333*	24 h	24 h
Test 2 (repeat)	10*, 33*, 333*	48 h	48 h
Present			
Test 1	10*, 33*, 100*	3 h	24 h
Test 2	10*, 33*, 100*	3 h	48 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		>100	>33	Negative
Test 2		>100	>33	Negative
Present				
Test 1		>100	>33	Negative
Test 2		>333	>33	Negative

Remarks - Results

The vehicle controls had acceptable mutant frequency values that were within the normal range for cultured human peripheral lymphocytes but at the high end of the historical values. The positive control materials induced marked increases in the mutant frequency indicating the satisfactory performance of the test and of the activity of the metabolising system.

Precipitation of the notified chemical was observe at concentrations >33 µg/mL in Test 1 and Test 2 in the absence and presence of metabolic activation.

The test material did not induce any toxicologically significant or dose-related increases in the mutant frequency at any dose level, either with or without metabolic activation, in either the first or the second experiment using a dose range where the maximum dose level was limited by cytotoxicity of the notified chemical.

CONCLUSION

The notified chemical was not clastogenic to cultured peripheral human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY

NOTOX B.V. (2007c)

B.8. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE

Notified chemical (>95%)

METHOD

OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Directive 2004/73/EC B.42 Skin Sensitisation (Local Lymph Node Assay)

Species/Strain: Mouse/CBA strain
Vehicle: Acetone/olive oil 4:1
Remarks - Method: No significant protocol deviations

RESULTS

Concentration (% w/w)	*Proliferative response (Median DPM/animal)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	440	-
25	614	1.4
50	2047	4.7
100	3046	6.9
Positive Control		
5	474	1.3
10	547	1.5
25	1980	5.5

Remarks - Results

Slight erythema was noted among the animals treated at 50% and in all animals treated at 100%. No oedema was observed in any of the animals examined. The irritation of the ears as shown by the animals was considered not to have a toxicologically significant effect on the activity of the nodes.

The majority of nodes were considered normal in size, except for the enlarged nodes of three animals treated at 50% and three animals treated at 100%. No macroscopic abnormalities of the surrounding area were noted.

There were large outliers in all test groups except for the untreated group, therefore the median DPM of each group was used to calculate the Stimulation Index.

An EC3 value of 37.1% was calculated.

A positive control was not tested concurrently as part of this test. However, a previous test using α-Hexylcinnamaldehyde as positive control at concentrations up to 15% in Acetone: Olive oil (4:1) produced a stimulation index of 5.5 confirming the sensitivity of the assay to predict sensitising potential.

CONCLUSION

There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY

NOTOX B.V. (2008f)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test (1992).

EC Directive 92/69, C.4-C Biodegradation: Determination of the "Ready" Biodegradability: Carbon Dioxide Evolution Test Modified Sturm Test).

ISO 9439 "Water Quality - Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium - carbon dioxide evolution test (1999).

Inoculum	Activated sludge from a domestic sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Total Organic Carbon (TOC) analysis.

Remarks - Method

The notified chemical was tested in duplicate at a level of 17 mg/L, corresponding to a TOC level of 12 mg/L. A blank control in duplicate containing the inoculum only, a singular positive control containing sodium acetate and the inoculum, and a singular toxicity control containing the notified chemical, sodium acetate and the inoculum were conducted.

Determination of CO_2: The CO_2 produced reacted with the barium hydroxide in the gas scrubbing bottle and precipitated out as barium carbonate. The amount of CO_2 produced was determined by titrating the remaining $Ba(OH)_2$ with 0.05 M standardized HCl solution.

Since the organic carbon content of the test substance could not be calculated, a sample of the pure test substance was taken for determination of the Total Organic Carbon (TOC) content (69.98%). The $ThCO_2$ was calculated to be 2.57 mg CO_2/mg.

RESULTS

Notified chemical		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
1	0	1	0
4	9	4	25
13	42	13	60
29	55	29	77

Remarks - Results

All the test validity criteria were met.

The notified chemical reached 55% degradation at the end of the test. Thus, the criterion for ready biodegradability (at least 60% biodegradation within a 10-day window) was not met. Based on the extrapolation of the curves for degradation, 60% biodegradation would be reached after 30-31 days.

The notified chemical is not considered readily biodegradable based on the degree of degradation achieved in the test. However, the significant degree of degradation suggests the chemical has potential of biodegradability.

CONCLUSION: The notified chemical is not readily biodegradable.

TEST FACILITY NOTOX B.V. (2007d)

C.1.2. Biodegradability in seawater

TEST SUBSTANCE Notified chemical (75%)

METHOD OECD TG 306: Biodegradability in Seawater: Closed Bottle Method
Exposure Period 28 days
Auxiliary Solvent None
Analytical Monitoring Biochemical oxygen demand (BOD) was determined
Remarks - Method The notified chemical was tested in duplicate at 1.86 mg/L, corresponding to theoretical oxygen demand (ThOD) 4.73 mg O_2/L. A blank control in duplicate containing the medium only, a positive control in duplicate containing sodium benzoate (2.49 mg/L or ThOD 4.00 mg O_2/L) and the medium, and a singular toxicity control containing the notified chemical (1.86 mg/L), sodium benzoate (1.25 mg/L) and the medium were conducted. The degree of degradation was calculated as the percentage fraction of BOD to ThOD.

Seawater with a salinity of 34% was used with the possible particles removed. It was supplemented with nutrients, presumably according to the method recommended in the Guideline.

RESULTS

Notified chemical		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	56	7	79
14	66	14	84
21	67	21	86
28	71	28	90

Remarks - Results All the test validity criteria were met.

A degree of degradation of 56% at day 7 and 66% at day 14 were achieved. Based on the test results, the test substance has potential for biodegradation in the marine environment. The notified chemical is considered likely to have a potential for biodegradation in the marine environment since the test substance mainly consisted of the notified chemical.

CONCLUSION The notified chemical is likely to have potential for biodegradation in the marine environment.

TEST FACILITY Rogaland Research Environmental Laboratory (2002)

C.1.3. Bioaccumulation

TEST SUBSTANCE Notified chemical (75%)

METHOD OWTC SOP 108 (in-house method).

Species *Mytilus edulis* (Blue Mussels)
Exposure Period Exposure: 10 days Depuration: 20 days
Auxiliary Solvent None
Concentration Range Saturated solution
Analytical Monitoring Gas Chromatography-mass-spectrometry (GC-MS) for concentration analyses
Remarks - Method The test substance was prepared for testing according to OWTC SOP 108 that was written to comply with the general provisions of OECD TG 305 A-E, modified with the approval of CEFAS Fisheries Laboratory to be

applicable to *Mytilus edulis*.

The test substance was adsorbed to fine glass wool within a glass column inserted into a round glass flask. For inflowing, filtered seawater was recirculated through the glass column from top to bottom to ensure that the water abstracted from the outflow of the flask was fully saturated with the soluble components of the notified chemical. The outflow was directed to a covered header tank to ensure thorough mixing and even distribution of flow and concentration to the exposure vessels.

A minimum of 50 animals were used for each test to ensure at least 5 mussels for each of the ten sampling occasions.

Exposure vessels were observed daily to permit the removal of any dead animals. The bioconcentration factor (BCF) was calculated on both a dry weight and a lipid weight basis.

RESULTS

Bioconcentration Factor	4.45 on a dry weight basis and 5.75 on a lipid weight basis
CT50	
Remarks - Results	The test validity criteria (i.e. water quality, mussel survival and behaviour) were met. On day 15 (after 5 days depuration) the levels of the test substance measured in tissue were higher than that at day 10, which is considered unusual. There was the presence of detectable quantities in the water. The test substance was composed of esters of fatty acids with polyol, which are similar and difficult to distinguish from the materials occurring naturally in mussel tissue. Therefore, the reported tissue concentrations are likely to over-estimate the accumulation of the test substance. The calculated BCF for the test substance is 4.45 on a dry weight basis and 5.75 on a lipid weight basis. However, based on the above considerations, and the fact that the test substance contained 75% of the notified chemical, these results are unlikely to be adequate estimates of the bioaccumulative potential for the notified chemical.

CONCLUSION The notified chemical may have potential for bioaccumulation

TEST FACILITY Environment & Resource Technology Ltd (1997)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish – Study 1

TEST SUBSTANCE Notified chemical

METHOD OECD TG 203 Fish, Acute Toxicity Test – Semi-static – 96h (1993), modified to marine conditions.

OSPAR / PARCOM Protocols on Methods for the Testing of Chemicals Used in the Offshore Industry 1995 (OSPAR, 1995).

Species	*Scophthalmus maximus* (Turbot)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Not reported.
Analytical Monitoring	None
Remarks – Method	After a range-finding study, turbots were exposed to test solutions of nominal concentrations 560, 1000 and 1800 mg/L at 15±1.5˚C and pH 8.2-8.4. For the solution preparation, the required amount of homogenised sample was added to seawater, mixed for 20-24 hours and then allowed to separate for 4 hours. The sub-natant liquid was drawn off and used for the

test (water accommodated fractions, WAFs). The salinity of the seawater used was 32 to 35 g/L sodium chloride.

The test and control solutions were renewed at 48 hours, and the remaining live animals were transferred to freshly prepared test solutions.

RESULTS

Concentration mg/L *Nominal*	*Number of Fish*	*Mortality* *1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	7	0	0	0	0	0
560	7	0	0	0	0	0
1000	7	0	0	0	0	0
1800	7	0	0	0	0	0

LL50 > 1800 mg/L at 96 hours (WAF).
NOEL 1800 mg/L at 96 hours (WAF).
Remarks – Results No abnormal behaviour of the turbot was recorded in any test solution at any time point. No mortality was observed through the study for all the tested levels.

The given LL50 values are based on nominal concentrations (WAF) instead of actual concentrations. Considering the low solubility in water, the notified chemical is not considered to be harmful to turbots up to the limit of its solubility in water.

CONCLUSION The notified chemical is not harmful to turbots up to the limit of its solubility in water.

TEST FACILITY Chemex Environmental International Limited (2004)

C.2.2. Acute toxicity to fish – Study 2

TEST SUBSTANCE Notified chemical (75%)

METHOD OECD TG 203 Fish, Acute Toxicity Test - Semi-static-96h (1993), modified to marine conditions.

OSPAR / PARCOM Protocols on Methods for the Testing of Chemicals Used in the Offshore Industry 1995 (OSPAR, 1995).

Species *Scophthalmus maximus* (Turbot)
Exposure Period 96 hours
Auxiliary Solvent None
Water Hardness Not reported.
Analytical Monitoring None
Remarks – Method After a range-finding study, turbots were exposed to test solutions of nominal concentrations at 320, 560, 1000 and 1800 mg/L at 15±1.5˚C and pH 7.9-8.3. For the solution preparation, the required amount of homogenised sample was added to seawater, mixed for 20-24 hours and then allowed to separate for 4 hours. The sub-natant liquid was drawn off and used for the test (water accommodated fractions, WAFs). The salinity of the seawater used was 32 to 35 g/L sodium chloride.

The test and control solutions were renewed at 48 hours, and the remaining live animals were transferred to freshly prepared test solutions.

RESULTS

Concentration mg/L *Nominal*	*Number of Fish*	*Mortality* *1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	7	0	0	0	0	0
320	7	0	0	0	0	0

560	7	0	0	0	0	0
1000	7	0	0	0	0	0
1800	7	0	0	0	0	0

LL50 > 1800 mg/L at 96 hours (WAF).
NOEL 1800 mg/L at 96 hours (WAF).
Remarks – Results No abnormal behaviour of the turbot was recorded in any test solution at any time point. No mortality was observed through the study for all the tested levels.

The given LL50 values are based on nominal (WAF) instead of actual concentrations. Considering the low solubility in water, the notified chemical is not considered to be harmful to turbots up to the limit of its solubility in water.

CONCLUSION The notified chemical is not harmful to turbots up to the limit of its solubility in water.

TEST FACILITY Chemex Environmental International Limited (2002)

C.2.3. Acute toxicity to aquatic invertebrates – Study 1

TEST SUBSTANCE Notified chemical

METHOD ISO 14669 (1998): Determination of acute lethal toxicity to marine copepods (*Copepoda, Crustacea*).

OECD 2000: Guidance Document on aquatic toxicity testing of difficult substances and mixtures. OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 23. ENV/JM/MONO (2000)6.

Species *Acartia tonsa* (Marine crustacean)
Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring TOC Analysis: samples with loading 101 and 1000 mg/L and the control were taken at the start of the test.
Remarks - Method *Acartia tonsa* was exposed to the notified chemical of water accommodated fractions (WAFs) at loading rates 101, 180, 321, 561 and 1000 mg/L at 20 ± 1˚C. Natural seawater (salinity adjusted by distilled water to 32‰) was used to prepare the WAF. The notified chemical was agitated in water for 23 h in the dark at 21°C, followed by settling for 1 h, and then the WAFs were drawn with a pipette to avoid the settled material at the bottom of the flasks. All WAFs were slightly turbid and were filtered through GF/C glass fibre filters to remove non-settling suspended material.

A reference control was conducted using 3,5-dichlorophenol. Four test vessels were used for each test and 16 test vessels were used for the control with 5 – 9 animals in each vessel.

RESULTS

Concentration mg/L Nominal	*Number of Acartia tonsa*	*Number Immobilised*	
		24 h	*48 h*
Control	146	0	1
101	28	1	3
180	27	0	0
321	26	0	4

561	26	0	2
1000	29	0	2

EL50	>1000 mg/L at 48 hours (WAF)
NOEL	1000 mg/L at 48 hours (WAF)
Remarks - Results	No clear does-responding effect was observed at levels up to 1000 mg/L. The mortality after 48 hours reached a maximum of 15% at loading level 321 mg/L but decreased to about 7% at 561 mg/L and 1000 mg/L. The EL50 is considered to be > 1000 mg/L. The measured TOC is 1.0 mg/L for the control (seawater), 4.8mg /L for the 101 mg/L WAF and 34.8 mg /L for the 1000 mg/L WAF, indicating that the concentration of the notified chemcial in all the test sulotions are well above its solubility level. The notified chemical is not considered to be harmful to *Acartia tonsa* up to the limit of its solubility.
CONCLUSION	The notified chemical is not harmful to *Acartia tonsa* up to the limit of its solubility in water.
TEST FACILITY	Norwegian Institute for Water Research (2004a)

C.2.4. Acute toxicity to aquatic invertebrates – Study 2

TEST SUBSTANCE	Notified chemical (75%)
METHOD	ISO 14669 (1997): Water quality - Determination of acute lethal toxicity to marine copepods (*Copepoda, Crustacea*)
Species	*Acartia tonsa* (Dana)
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Test concentration not measured
Remarks - Method	*Acartia tonsa* was exposed to the test substance in four test vessels of water accommodated fractions (WAFs) at loading rates 12.9, 34.4, 99.1, 333, 1030 and 3200 mg/L at 20±2˚C. Filtered (through a GF/C filter) natural seawater (salinity 34‰) was used to prepare the WAF. The test substance was agitated in water for 20 hours, followed by settling for 4 hours. Samples for each test were taken from the middle of the water phase. A blank control and reference control was conducted using 3,5-dichlorophenol at 1 mg/L in 6 vessels. 5-6 animals were used in each vessel for each of the tests.

RESULTS

Concentration mg/L (WAF) Nominal	*Number of Acartia tonsa*	*Number Immobilised*	
		24 h	*48 h*
Control	30	0	0
12.9	20	0	0
34.4	20	0	0
99.1	20	0	0
333	20	0	0
1030	20	0	1
3200	21	0	3

EL50	>3200 mg/L at 48 hours (WAF)

NOEL	1030 mg/L at 48 hours (WAF)
Remarks - Results	All validity criteria for the test were met. The mortality at 48 hour reached a maximum of 14% at loading level 3200 mg/L. The EL50 is considered to be > 3200 mg/L. The NOEL was calculated by single-factor ANOVA followed by Bonferronis procedure for comparing each concentration mean with the control mean. Considering the low water solubility, the test substance is not considered to be harmful to *Acartia tonsa* up to the limit of its solubility. Some effects observed at higher concentrations may be due to physical effects of the undissolved particles of the test substance in the medium. The notified chemical is not considered harmful to *Acartia tonsa* up to the limit of its solubility given the majority (75%) of the test substance was the notified chemical.
CONCLUSION	The notified chemical is not harmful to *Acartia tonsa* up to the limit of its solubility in water.
TEST FACILITY	Rogaland Research Environmental Laboratory (2001a)

C.2.5. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 211 "*Daphnia magna*, Reproduction Test", Adopted: October 2008- 21-day – Semi Static. EC No 440/2008 of 30 May 2008, Part C: Methods for the determination of ecotoxicity, Publication No. L142, C.20. "Daphnia magna Reproduction Test". ISO International Standard 10706: "Determination of long term toxicity of substances to *Daphnia magna* Straus (*Cladocera, Crustacea*)", 2000-03-30.
Species	*Daphnia magna*
Exposure Period	21 d
Auxiliary Solvent	None
Water Hardness	180 mg $CaCO_3$ /L
Analytical Monitoring	TOC analysis of all freshly prepared test concentrations and the control was performed at days 0, 7, 14 and 19.
Remarks - Method	Preparation of test solutions started with a loading rate 100 mg/L that was magnetically stirred in test medium for two days, resulting in a hazy dispersion with undissolved particles and a floating layer. The middle fraction of the dispersion was then siphoned over a glass fibre filter to remove the majority of undissolved particles. The resulting filtrate was still slightly hazy. The lower test concentrations (1.0, 3.2, 10 and 32% of the filtrate) were prepared by subsequent dilution of the filtrate in the test medium. 10 vessels per test concentration and 20 vessels for an untreated group were used. Each of the vessels contained only one neonate *Daphnia magna* in 50 mL test medium.

Nominal loading, parental mortality, cumulative mean number of offspring released [a] and mean total body length of survival parental daphnids

Test Day 21

Loading Rate (mg/L) Nominal	Actual[b]	Parental Mortality (%)	Mean Number of Offspring Released per female (SD)	Mean Total Body Length in mm (SD)
Control	0	10	145.4 (12.6)	4.34 (0.29)
1.0	< 0.14	40	138.8 (14.9)	4.31 (0.05)
3.2	0.57	10	151.3 (12.9)	4.41 (0.12)
10	2.3	0	164.1 (23.0)	4.40 (0.19)
32	7.9	10	139.7 (22.7)	4.30 (0.18)
100	26.1	90	15.0 9 (-)	3.29 (-)
EL50 (mg/L, nominal)		52[c,e]	> 32	> 32
NOEL (mg/L, nominal)		32[e]	32[d]	32

[a] Offspring produced by daphnids dead before 21 days were counted.
[b] Based on measured mean TOC for Day 0, 7, 14 and 19.
[c] Calculated by Finney probit analyses.
[d] Calculated by Toxstat
[e] These endpoints appear to be based on a physical effect and not a toxic effect.

Remarks - Results

All the test validity criteria were met.

No significant effects on the mortality of daphnids were observed at loading rates up to 32 mg/L, which corresponds to an actual concentration of 7.9 mg/L, a value that is well above the solubility (< 1 mg/L) of the notified chemical in water. Therefore, the notified chemical is not considered to be harmful to daphnids up to the limit of its solubility. The effects on mortality observed at the highest loading rate is likely to be from the physical effects of the undissolved particles in the medium, and therefore, the results from this test concentration are considered invalid with respect to the toxicity of the notified chemical.

A significant parental mortality of 40% was observed at a loading rate of 1.0 mg/L. Considering no other significant mortality was observed in the range 0 – 32 mg/L, this result is considered to be an outlier and is therefore not taken into account with respect to the determination of the endpoints.

CONCLUSION

The notified chemical is not chronically harmful to daphnids up to the limit of its solubility in water.

TEST FACILITY

NOTOX B.V. (2009)

C.2.6. Algal growth inhibition test – Study 1

TEST SUBSTANCE

Notified chemical

METHOD

ISO 10253 (1998): Water Quality-Marine growth inhibition test with *Skeletonema costatum* and *Phaeodactylum tricornutum.*

OECD 2000: Guidance Document on aquatic toxicity testing of difficult substances and mixtures. OECD Environmental Health and Safety Publications Series on Testing and Assessment No. 23. ENV/JM/MONO (2000)6.

Species: *Skeletonema costatum* (Marine alga)
Exposure Period: 72 hours
Concentration Range: Nominal: 100, 180, 320, 560 and 1000 mg/L
Auxiliary Solvent: None
Water Hardness: Not reported
Analytical Monitoring: TOC Analysis for concentration of the notified chemical.
Cells were counted using Coulter Multisizer electronic particles counter.
Remarks - Method: WAFs of five different loading levels were tested. Three replicates for

each loading level and six replicates for the control were conducted. To prepare the WAFs, the notified chemical in the test medium at each different level was shaken for 24 h at 21˚C, allowed to settle for 1 h and drawn with a pipette to avoid the settled material at the bottom of the flasks. All WAFs were filtered through glass fibre filters to remove non-settling material. Test algae were added to obtain a cell density of approximately 5×10^6 cells/L.

The test medium used was ISO 10253 medium based on filtered (0.45 µm) natural seawater (salinity 34‰). Nutrients were added according to ISO10253.

RESULTS

Biomass (WAF)		*Growth (WAF)*	
E_bL50	*NOEL*	*E_rL50*	*NOEL*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
> 1000	180	> 1000	180

Remarks - Results

The measured TOC at the start of the test was 6.0, 10.0 and 72.0 mg/L for the control seawater, the 100 mg/L and 1000 mg/L WAFs, respectively. These values are equivalent to 8.6, 14.3 102.9 mg notified chemical /L, which are higher than the solubility of the notified chemcial in water.

Inhibition of the growth was observed at levels > 180 mg/L (WAF). Therefore, the no observable effect loading (NOEL) is determined to be 180 mg/L (WAF). The E_rL50 and E_bL50 and were determined to be > 1000 mg/L (WAF).

Based on the test results, the notified chemical is not considered to be harmful to alga up to the limit of its solubility. The effects at higher levels are considered to be from physical effects of the undissolved particles of the notified chemical in the test medium. However, it is not reported if particulate matter was present in the WAFs after glass wool filtration.

CONCLUSION

The notified chemical is not harmful to alga up to the limit of its solubility in water.

TEST FACILITY

Norwegian Institute for Water Research (2004b)

C.2.7. Algal growth inhibition test – Study 2

TEST SUBSTANCE

Notified chemical (75%)

METHOD

ISO 10253 (1998): Water Quality-Marine growth inhibition test with *Skeletonema costatum* and *Phaeodactylum tricornutum.*

Species	*Skeletonema costatum* (Marine alga)
Exposure Period	72 hours
Concentration Range	Nominal: 3.2, 10.4, 32.4, 100, 320 and 1040 mg/L (WAFs)
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Cell growth (biomass) was measured by fluorescence.
Remarks - Method	The study was conducted at five loading rates in three replicates and six replicates for a blank control at 20±2˚C and pH 8-8.3. To prepare WAFs, the notified chemical in the growth medium was stirred for 20 h, and allowed to settle for 4 h. Samples for testing were drawn from the middle of the water phase. The dilution liquid used was filtered (GF/C filter) natural seawater (sanity 34‰) that was heated to 75˚C prior to use.

Nutrients were added according to ISO10253.

A reference control with 3,5-dichlorophenol was performed in triplicate at 1.5 mg/L.

The E_bC50 was calculated by the use of the computer programme TOXEDO developed by VKI (Denmark), assuming a logarithmic normal distribution of data.

RESULTS

Biomass (WAF)	
E_bL50 mg/L at 72 h	*NOEL mg/L*
216.3	10.4

Remarks - Results

All criteria for the test validity were met.

Inhibition of the growth was observed at levels ≥ 32.4 mg/L (WAF). Therefore, the no observable effect loading (NOEL) is determined to be 10.4 mg/L (WAF). The E_bL50 was determined to be 216.3 mg/L (WAF).

Considering the low water solubility, and based on the test results, the test substance is not considered to be harmful to alga up to the limit of its solubility in water. The effects at higher levels are considered to be from physical effects of the undissolved particles of the test substance in the medium. Given the test substance is mainly composed of the notified chemical (75%), the notified chemical is considered not harmful to alga up to the limit of its solubility in water, which is consistent with the conclusion obtained from the previous studies. However, it is not reported if particulate matter was present in the WAFs used for the test.

CONCLUSION

The notified chemical is not harmful to alga up to the limit of its solubility in water.

TEST FACILITY

Rogaland Research Environmental Laboratory (2001b)

C.2.8. Inhibition of microbial activity

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 209 Activated Sludge, Respiration Inhibition Test (1984).

EC Directive 87/302/EEC C.11 Biodegradation: Activated Sludge Respiration Inhibition Test.

ISO 8192, Water Quality - Test for inhibition of oxygen consumption by activated sludge for carbonaceous and ammonium oxidation (2007).

Inoculum: Activated sludge from a domestic sewage treatment plant

Exposure Period: 3 hours

Concentration Range: Nominal: 100 mg/L

Remarks – Method: A nominal loading rate of 100 mg/L was tested in duplicate at 18.9-20.0˚C, pH 7.7 and oxygen concentration 6.7 mg/L. To prepare the test solutions, a solution of initial loading rate 200 mg/L in Milli-RO water was treated with ultrasonic waves for 10 minutes, followed by a stirring period of 24-25 hours in the test bottle. Subsequently, synthetic sewage feed and sludge were added resulting in a final loading rate of 100 mg/L. Optimal contact between the test substance and test medium was ensured

	by applying continuous aeration and stirring. A blank control in duplicate and reference controls with 3,5-dichlorophenol at 1.0, 3.2 10 and 32 mg/L were performed.
RESULTS	
IC50	> 100 mg/L
NOEC	100 mg/L
Remarks – Results	All the criteria for the test validity were met. The IC50 for the reference substance was determined to be 5.7 mg/L (95% confidence limits 2.4-13.6 mg/L), which is in the accepted range of 5-30 mg/L. The difference between the controls was ≤ 10%, which is within the limit of 15%. No significant inhibition to the respiration rate of the sludge was detected at the test level. Therefore, the notified chemical is not considered to be harmful to sewage sludge microorganisms.
CONCLUSION	The notified chemical is not harmful to sewage sludge microorganisms.
TEST FACILITY	NOTOX B.V. (2007e)

BIBLIOGRAPHY

Chemex Environmental International Limited (2002) The toxicity to Turbot (*Scophthalmus maximus*) of Radiagreen EBL. Chemex Ref. no. ENV6110/050234. Chemex Environmental International Limited, Cambridge, UK. 25 July 2002 (Unpublished report provided by notifier).

Chemex Environmental International Limited (2004) The toxicity to Turbot (*Scophthalmus maximus*) of Radiagreen EBL Pentaerythritol fatty acid ester. Chemex Ref. no. ENV6998/080416. Chemex Environmental International Limited, Cambridge, UK. 20 October 2004 (Unpublished report provided by notifier).

Environment & Resource Technology Ltd (1997) Assessment of the bioconcentration factor (BCF) of the Fluid Finagreen EBL in the Blue Mussel *Mytilus edulis*. Study no. 192-6-1. Environment & Resource Technology Ltd, Orkney, UK. 3 September 1997 (Unpublished report provided by notifier).

Evans, H. (1984). Human Peripheral Blood Lymphocytes for the Analysis of Chromosome Aberrations in Mutagen Tests. *Handbook of Mutagenicity Test Procedures*, Eds. Kilbey, B., Legator, M., Nichols, W. and Ramel, C., 405-427, Elsevier Science Publishers B.V., Amsterdam.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

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

Norwegian Institute for Water Research (2004a) *Radiagreen EBL* (Pentaerythritol mono oleate base Polyol) Acute Toxicity to the Marine Crustacean *Acartia tonsa*. NIVA Study No. G055/3. Norwegian Institute for Water. Oslo, Norway. October 2004 (Unpublished report provided by notifier).

Norwegian Institute for Water Research (2004b) *Radiagreen EBL* (Pentaerythritol mono oleate base Polyol) Growth Inhibition of the marine alga *Skeletonema costatum*. NIVA Study No. G055/1. N Norwegian Institute for Water. Oslo, Norway. 30 September 2004 (Unpublished report provided by notifier).

NOTOX B.V. (2007a) Determination of Physico-Chemical Properties of Notified Chemical. Project 485705. NOTOX B.V. Hertogenbosch, The Netherlands. 14 November 2007 (Unpublished report provided by notifier).

NOTOX B.V. (2007b) Evaluation of the Mutagenic Activity of Notified Chemical in the *Salmonella Typhimurium* Reverse Mutation Assay and the *Escherichia Coli* Reverse Mutation Assay (with Independent Repeat). Project 485729. NOTOX B.V. Hertogenbosch, The Netherlands. 12 September 2007 (Unpublished report provided by notifier).

NOTOX B.V. (2007c) Evaluation of the Ability of Notified Chemical to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes (with Repeat Experiment). Project 485730. NOTOX B.V. Hertogenbosch, The Netherlands. 30 October 2007 (Unpublished report provided by notifier).

NOTOX B.V. (2007d) Determination of 'Ready' Biodegradability: Carbon Dioxde (CO_2) Evolution Test (Modified Sturm Test) of Notified Chemical. Project 485731. NOTOX B.V. Hertogenbosch, The Netherlands. 13 November 2007 (Unpublished report provided by notifier).

NOTOX B.V. (2007e) Activated Sludge Respiration Inhibition Test with Notified Chemical. Project 485732. NOTOX B.V. Hertogenbosch, The Netherlands. 13 September 2007 (Unpublished report provided by notifier).

NOTOX B.V. (2008a) Assessment of Acute Oral Toxicity with Notified Chemical in the Rat (Acute Toxic Class Method). Project 485721. NOTOX B.V. Hertogenbosch, The Netherlands. 2 January 2008 (Unpublished report provided by notifier).

NOTOX B.V. (2008b) Assessment of Acute Dermal Toxicity with Notified Chemical in the Rat. Project 485722. NOTOX B.V. Hertogenbosch, The Netherlands. 2 January 2008 (Unpublished report provided by notifier).

NOTOX B.V. (2008c) Primary Skin Irritation/Corrosion Study with Notified Chemical in the Rabbit (4-Hour Semi-occlusive Application). Project 485723. NOTOX B.V. Hertogenbosch, The Netherlands. 2 January 2008 (Unpublished report provided by notifier).

NOTOX B.V. (2008d) Acute Eye Irritation/Corrosion Study with Notified Chemical in the Rabbit. Project 485724. NOTOX B.V. Hertogenbosch, The Netherlands. 2 January 2008 (Unpublished report provided by notifier).

NOTOX B.V. (2008e) Repeated Dose 28-Day Oral Toxicity Study with Notified Chemical by Daily Gavage in the Rat. NOTOX B.V. Hertogenbosch, The Netherlands. 3 April 2008 (Unpublished report provided by notifier).

NOTOX B.V. (2008f) Project 485725 Assessment of Contact Hypersensitivity to Notified Chemical in the Mouse (Local Lymph Node Assay). Project 485726 (485727). NOTOX B.V. Hertogenbosch, The Netherlands. 27 March 2008 (Unpublished report provided by notifier).

NOTOX B.V. (2008g) Toxicokinetic Assessment of Notified Chemical. Project 485728. NOTOX B.V. Hertogenbosch, The Netherlands. 28 February 2008 (Unpublished report provided by notifier).

NOTOX B.V. (2009) *Daphnia Magna*, Reproduction test with Notified Chemical (Semi-Static). Project 490033. NOTOX B.V. Hertogenbosch, The Netherlands. 22 October 2009 (Unpublished report provided by notifier).

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

Oil & Gas Producers (2003) Environmental Aspects of the Use and Disposal of Non Aqueous Drilling Fluids Associated with Offshore Oil & Gas Operations. International Association of Oil & Gas Producers, Report No. 342, May 2003, <http://www.ogp.org.uk/>. Accessed 2010 May 18.

OSPAR (1995) OSPAR / PARCOM Protocols on Methods for the Testing of Chemicals Used in the Offshore Industry 1995.

Owen, B.A., Dudney, C.S., Tan, E.L., and Easterly, C.E., (1990) Formaldehyde in drinking water: Comparative hazard evaluation and an approach to regulation, *Regulatory Toxicology and Pharmacology*, **11**, 220.

Rogaland Research Environmental Laboratory (2001a) Test Report Acute Toxicity Test with the Marine Copepod *Acartia tonsa*. RF-Milijølab, Stavanger, Norway. 25 September 2001. (Unpublished report provided by notifier)

Rogaland Research Environmental Laboratory (2001b) Test Report Growth Inhibition Test with the Marine Alga *Skeletonema costatum*. RF-Milijølab, Stavanger, Norway. 25 September 2001. (Unpublished report provided by notifier)

Rogaland Research Environmental Laboratory (2002) Test Report Radiagreen EBL Test for Biodegradability in Seawater. RF-Milijølab, Stavanger, Norway. 26 June 2002. (Unpublished report provided by notifier)

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

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

US EPA (2009) Estimations Programs Interface Suite™ for Microsoft® Window, v 4.00. United States Environmental Protection Agency. Washington, DC, USA.