File No: STD/1464
STD/1465
STD/1466

May 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

STD/1464 Chemical 2 in Soltex Sodium Additive (Blown)
STD/1465 Chemical 1 in Soltex Potassium Additive
STD/1466 Chemical 2 in Soltex Potassium Additive (Blown)

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 Sustainability, Environment, Water, Population and Communities.

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

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

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1464 STD/1465 STD/1466	Chevron Phillips Chemicals Pty Ltd	Chemical 2 in Soltex Sodium Additive (Blown) Chemical 1 in Soltex Potassium Additive Chemical 2 in Soltex Potassium Additive (Blown)	ND*	≤ 150 tonne/s per annum	Component of drilling muds for conventional oil and gas well drilling

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

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

When used in the proposed manner, the notified chemicals are 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 chemicals are 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 engineering controls to minimise occupational exposure to the notified chemicals as introduced in the products:
  - Transfer of the chemicals in powder form should be carried out under well-ventilated conditions

- 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 chemicals as introduced in the products:
  - Avoid contact with eyes and skin
  - Avoid inhalation of dust
  - Empty bags outdoors only when facing down wind

- 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 chemicals as introduced in the products:
  - Impervious gloves
  - Goggles
  - Protective clothing
  - Respiratory protection if inhalation of dusts/aerosols is expected.

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 chemicals 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 chemicals should be disposed of to landfill.

Storage

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

Emergency procedures

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

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 chemicals 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 chemicals, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemicals are listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(1) of the Act; if
  - The notified chemicals are proposed to be used in on-shore drilling operations involving hydraulic fracturing.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemicals has changed from a component of drilling muds for conventional oil and gas well drilling, or is likely to change significantly;
  - the amount of chemicals being introduced has increased from 150 tonnes per annum, or is likely to increase significantly;
  - the chemicals have begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemicals on occupational health and safety, public health, or the environment.

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

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chevron Phillips Chemicals Australia Pty Ltd (ABN: 29 107 015 896)
Suite 409, Burke Road
CAMBERWELL VIC 3124

NOTIFICATION CATEGORY
STD/1465: Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Similar to a chemical that was previously assessed by NICNAS.

STD/1464: Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Chemical is being notified at the same time as a similar chemical.

STD/1466: Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Chemical is being notified at the same time as a similar chemical.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: molecular and structural formulae, molecular weight, and analytical data.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: vapour pressure, hydrolysis as a function of pH, partition coefficient, adsorption/desorption, dissociation constant, flash point, flammability, autoignition temperature, explosive properties, oxidising properties, acuter dermal and inhalation toxicity, skin and eye irritation, skin sensitisation and genotoxicity and acute fish toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
STD/1464: Asphalt, oxidised, sulfonated, sodium salt
STD/1465: Asphalt, sulfonated, potassium salt
STD/1466: Asphalt, oxidised, sulfonated, potassium salt

CAS NUMBER
STD/1464: 1394242-48-8
STD/1465: 1365116-88-6
STD/1466: 1394242-49-9

MOLECULAR FORMULA
STD/1464: Unspecified
STD/1465: Unspecified
STD/1466: Unspecified

MARKETING NAME(S)
Soltex Additive (product containing 60 - 85% of the notified chemical STD/1464)
Soltex Potassium Additive (product containing 60 - 85% of the notified chemical STD/1465 or STD/1466)

MOLECULAR WEIGHT
300 - 5,000 Da, based on the molecular weights of the components of asphalt.

ANALYTICAL DATA
Reference NMR, IR, HPLC, GC, GPC, UV spectra of an analogue chemical were provided.

3. COMPOSITION

DEGREE OF PURITY 100%

CHEMICAL COMPOSITION
The notified chemicals are asphalt derivatives (that is, asphalt has been reacted to result in a change to its chemical composition). Three chemical structures that are considered to be representative of the constituents of the notified chemicals (in terms of chain length and substitutions from the chain) have been used by the notifier for determination of several properties of the notified chemicals. However, the chemical compositions of the notified chemicals are highly dependent upon the asphalt used to produce them. The asphalt is sourced from various refineries in the United States (with the asphalt being of the same grade) and is the material remaining after all refinery products have been extracted from cracked crude oil. The notifier has stated that the use of the same grade of asphalt for synthesis of the notified chemicals should ensure consistency in its composition. That is, the nature and identity of the various chemicals present in the asphalt are not expected to vary between batches, although they may be present at different relative concentrations. However, other information indicates that the exact chemical composition of asphalt is dependent on the chemical complexity of the original crude petroleum and the refining process. The composition of the crude petroleum may vary between oil fields and even within the same oil field (at different locations). The refining process can result in changes to the physical properties of the asphalt; however, its chemical nature only changes if thermal cracking occurs. Further information about asphalt can be found in several literature sources (CICAD, 2004; HPV, 2006).

Elemental analyses indicate that most asphalts typically contain 79 - 88% (w/w) carbon, 7 - 13% hydrogen, up to 3% nitrogen, up to 8% sulfur, up to 8% oxygen and trace amounts of vanadium, nickel, aluminium and silicon. The major chemical groups present within asphalt are as follows:

a) Asphaltenes (5 - 25% by weight of asphalt): highly condensed aromatic compounds comprised of one or two chromophores containing 4 - 10 fused rings in each, and a significant number of alkyl substituents. Molecular weight typically 2,000 - 5,000.
b) Resins (15 - 25% by weight of asphalt): heterogeneous polar aromatic compounds with small amounts of oxygen, nitrogen and sulfur. Molecular weight typically 800 - 2,000.
c) Aromatic oil components (45 - 60% by weight of asphalt): compounds with aromatic and naphthenic-aromatic nuclei with side chain constituents. These contain mainly carbon, hydrogen and sulfur, and small amounts of oxygen and nitrogen. Molecular weight 500 - 900.
d) Saturated oil components (5 - 20% by weight of asphalt): mainly long chain saturated hydrocarbons with some branched chain compounds, alkyl aromatics with long side chains and cyclic paraffins (naphthenes). Molecular weight 500 - 1,000.

The notified chemicals are Unknown or Variable compositions, Complex reaction products and Biological materials (UVCBs) and meet the similarity criteria for a group assessment.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 ºC AND 101.3 kPa: Coarse black powder with no odour

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 800°C	Measured (analogue chemical)
Boiling Point	~739 - 1,277°C at 101.3 kPa	Calculated (HPV, 2006)
Density	1,435 kg/m^3 at 25°C	Measured (analogue chemical)
Vapour Pressure	<2 × 10^{-7} kPa	Estimated (HPV, 2006)
Water Solubility	≥ 4.8% w/w at 20°C, pH 10	Estimated for the analogue
Hydrolysis as a Function of pH	Not determined	Not expected to hydrolyse under the environment conditions based on the chemicals' structure
Partition Coefficient (n-octanol/water)	log Pow < 0 at 20°C	Estimated for the water soluble components of the analogue
Adsorption/Desorption	Not determined	Water soluble components are not expected to adsorb to sediment or soil based on the notified

		chemicals' structure
Dissociation Constant	Not determined	The notified chemicals are salts and will be ionised at the environmental pH range of 4 - 9.
Surface tension	61.0 mN/m	Measured
Particle Size	Inhalable fraction (< 100 μm): 28% Respirable fraction (< 10 μm): 2.6%	Measured (analogue chemical)
Flash Point	> 620°C	Estimated (HPV, 2006)
Flammability	Not determined	Not expected to be flammable based on high flash point and low vapour pressure.
Autoignition Temperature	Not determined	Not expected to undergo autoignition (HPV, 2006)
Explosive Properties	Not determined	Unlikely to contain explosophores
Oxidising Properties	Not determined	Does not contain oxidising groups

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties of a similar chemical previously assessed by NICNAS, refer to Appendix A.

Explosive properties

The major chemical groups present within asphalt, as described in Section 3, are unlikely to contain functional groups that are known to confer explosive properties. However, it is noted that the presence of chemical components within asphalt that contain known explosophores cannot be ruled out, although these are only likely to be present at low levels within the notified chemicals. Therefore, the notified chemicals are not expected to exhibit explosive properties.

Reactivity

The notified chemicals are expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified chemicals are 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 CHEMICALS (100%) OVER NEXT 5 YEARS

The notified chemicals will be imported into Australia as a component of products at concentrations of 60 - 85%.

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

Year	*1*	*2*	*3*	*4*	*5*
*Tonnes**	20 - 150	20 - 150	20 - 150	20 - 150	20 - 150

* Combined total of the three notified chemicals

PORT OF ENTRY

Adelaide, Darwin, Dampier, Fremantle, Broome, Melbourne, Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS

The products containing the notified chemicals will be supplied to drilling fluids service companies and then sold to end user mining companies.

TRANSPORTATION AND PACKAGING

The products containing the notified chemicals will be imported in polyethylene lined paper bags (11.3 or 22.6 kg). They will be transported to on-shore drilling sites by truck on shrink-wrapped pallets, and by ship to off-shore sites in steel containers containing a few pallets.

USE
The notified chemicals will be used as a component of a shale/well formation stabiliser in drilling muds during on-shore and off-shore conventional oil and gas well drilling operations. It is used for maintaining the integrity of the formation of the wells during drilling operations. The majority of off-shore drilling will occur in the Northern Territory and possibly the North West shelf of Western Australia. The notified chemicals will not be used for coal seam gas applications.

OPERATION DESCRIPTION
It is estimated that approximately 2.5 tonnes of the notified chemicals will be used during a single drilling operation. In addition, the use is expected to be limited to thirty oil and gas wells per year for the next five years.

At the drill site, workers will cut open the imported product bags containing the notified chemicals (60 - 85% concentration) at one end and manually empty the contents into a hopper. The bottom of the hopper is connected to a pipe/tube through which the drilling mud is transported under pressure and at high speed to the centre of the drill shaft. The transport of the mud pulls in the products containing the notified chemicals from the hopper by the Venturi effect and mixes the notified chemicals into the drilling mud (notified chemicals will be present at concentrations of approximately 0.4% in the drilling mud at this stage of the process). The hopper will be rinsed with water to ensure that residual products enter the delivery pipe. After drilling operations, the drilling mud is circulated out of the hole and cools as it returns to the surface, and is expected to be 37 - 66^{o}C when it reaches the surface.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS
Exposure of transport and warehouse workers to the notified chemicals is not expected.

At the end-use sites, dermal, ocular and inhalation exposure of workers to the notified chemicals (at concentrations up to 85%) may occur during emptying of the Soltex additive products in powder form into the hopper. A proportion of the powder is expected to be of respirable particle size. Exposure is likely to be minimised as the suction created by the Venturi effect should act to reduce the quantity of dust released during manual pouring of the products. In addition, such operations will be performed in well ventilated areas and it is expected that workers will wear skin, eye and respiratory protection, further reducing exposure to the notified chemicals. Worker exposure to drilling mud containing up to 0.4% of the notified chemicals may also occur after drilling, when the mud is returned to the surface for disposal.

6.1.2. Public Exposure
The public are not likely to be exposed to the notified chemicals as they will only be used by workers in the drilling industry.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on a similar chemical previously assessed by NICNAS are summarised in the following table. For full details of these studies, together with the newly provided mutagenicity - *in vitro* mouse lymphoma assay, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Low oral toxicity LD50 > 5,000 mg/kg bw
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Slightly irritating
Mouse, skin sensitisation – Local lymph node assay	No evidence of sensitisation
Rat, repeat dose oral toxicity with reproduction/developmental toxicity screening	NOEL = 1,000 mg/kg/day
Mutagenicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – *in vitro* mammalian chromosome aberration test	Non genotoxic
Mutagenicity – *in vitro* mouse lymphoma assay	Non mutagenic

The toxicological investigations summarised above were performed on different batches of the analogue chemical. There may be some variability in chemical composition between different batches, perhaps with varied levels of chemicals possessing functional groups of concern. However, it is expected that such variations would be minor and are unlikely to result in significant changes to the toxicological properties of the notified chemicals.

Toxicokinetics, Metabolism and Distribution

The notified chemicals are complex mixtures; as such, the pharmacokinetic behaviour will be dependent on the properties of the individual constituents. It is therefore considered inappropriate to generalise the extent of chemical absorption, distribution and metabolism. The statements below, regarding the expected behaviour of the notified chemicals, are based on the properties of the bulk material; however, the presence of other chemicals in the mixture (expected to be of low concentration) for which these predictions do not hold, cannot be ruled out.

The notified chemicals are not expected to be absorbed dermally, due to their high molecular weight and large molecular size, low water solubility and negligible vapour pressure.

The absence of significant toxicological effects following oral administration of the analogue chemical (in the acute oral toxicity study and repeat dose oral toxicity study) suggests that absorption from the gastrointestinal tract is minimal. This is further supported by predictions based on the high molecular weight and low water solubility of the notified chemicals.

No data was submitted on the inhalation toxicity of the notified chemicals. There is potential for inhalation of the notified chemicals, given the significant proportion that is of inhalable size [inhalable fraction (< 100 μm): ~28%] in the analogue. However, based on the particle size of the analogue, following inhalation, the majority of the notified chemicals are expected to be deposited in the nose or oral pharynx and would be unable to penetrate tissues due to the small proportion of respirable particles (~2.6%) (Klassen, 1996). The smaller particles may eventually be coughed or sneezed out of the body, cleared from the lungs; some may be transported to ciliated airways or into the pulmonary interstitium and lymphoid tissues. Some of it may be retained in the pulmonary interstitium, and a small amount may be transported to the blood.

Acute Toxicity

The analogue chemical previously assessed was found to be of low acute oral toxicity in rats (LD50 > 5,000 mg/kg bw) based on two separate studies performed on different batches.

No data was submitted on the acute dermal toxicity of the notified chemicals. As noted above, the notified chemicals are not expected to be dermally absorbed.

Irritation and Sensitisation

The analogue chemical previously assessed was found to be slightly irritating to the skin and eyes. In addition, a local lymph node assay (LLNA) resulted in no evidence of sensitisation. However, it is noted that the notified chemicals are likely to contain a number of structural moieties that are known alerts for irritation/corrosion (Hulzebos, 2003; Hulzebos, 2005) and sensitisation (Barratt, 1994).

Repeated Dose Toxicity and Toxicity for Reproduction

There were no toxicologically significant changes observed in the repeat dose oral toxicity study on the analogue chemical, resulting in an NOEL of 1,000 mg/kg/day. This study also examined effects on reproduction/ development, resulting in no significant toxicological observations and a NOEL of 1,000 mg/kg/day.

Mutagenicity

The analogue chemical produced negative results in the three *in vitro* mutagenicity/genotoxicity tests performed.

Carcinogenicity

The notified chemicals and the analogue chemical previously assessed are asphalt derivatives. Asphalt was classified by IARC in 1987 as a Category 3 carcinogen (IARC 1987). A re-evaluation in 2011 resulted in changes to the carcinogen categories for occupational exposure to some types of bitumens (also known as asphalt in some countries). The revised IARC classifications do not directly apply to the notified chemicals and

no carcinogenicity studies are available for the notified chemicals or the analogue. Carcinogenic concern may relate to the levels of polycyclic aromatic hydrocarbons (PAHs) (Lauby-Secretan et al 2011) which are stated to be present only at very low levels in the notified chemicals (< 15 ppm). However similar sulfonated derivatives may occur at higher concentrations and the effect of this functional group on potential carcinogenicity is not known.

It is noted that carcinogenicity concerns for bitumens (asphalts) are focussed on their use at higher temperatures where fumes may be emitted. The notified chemicals are used differently from other asphalts. In particular, the notified chemicals are not heated during well operations at temperatures where volatile emissions may occur. The negative results for genotoxicity in three *in vitro* studies on the analogue chemical are further indication of a low concern for carcinogenicity for the notified chemicals.

Related Chemicals
Long chain aliphatic hydrocarbons are a major component of asphalt. Following inhalation of such chemicals, hydrocarbons of 9 - 16 carbon atoms were found to be absorbed in the blood, brain, liver, kidneys and fat of rats. They are expected to be oxidatively metabolised and slowly eliminated in the urine and faeces (CICAD, 2004). Polycyclic aromatic hydrocarbons are also a major component of asphalt. Following inhalation, ingestion, or skin contact, they are expected to be metabolised and subsequently eliminated by urinary or biliary excretion. Whole body studies in rodents have also demonstrated detectable levels of polycyclic aromatic hydrocarbons in the majority of internal organs (CICAD, 2004).

Asphalt and chemicals that are structurally similar to some components of the notified chemicals have been tested for acute toxicity. They were generally found to be of low acute oral, dermal and inhalation toxicity (HPV, 2006). Dermal repeat dose toxicity studies have been performed using samples of asphalt. Signs of systemic toxicity were not reported; however, effects were seen that included decreased body weight gain and food intake, as well as skin effects (HPV, 2006).

Observations on Human Exposure
Several human studies have been performed to evaluate the effects of asphalt, many of which have been summarised in the CICAD document on asphalt (CICAD, 2004). The results of these studies are somewhat mixed.

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

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Available toxicological data on an analogue chemical previously assessed by NICNAS suggests that the notified chemicals are of low hazard. Concerns for carcinogenicity have been raised for related chemicals under conditions where volatile emissions may occur; however this is not expected to occur in the drilling scenarios where the chemicals will be used. Negative genotoxicity studies on the analogue chemical are an indication of a low concern for carcinogenicity for the notified chemicals.

The highest exposure of workers to the notified chemicals (concentrations up to 85%) is likely to occur during transfer of the products in powder form into the hopper (dermal, ocular and inhalation) as they are incorporated in the drilling mud. The particle size of the notified chemicals is not known, however based on the particle size distribution of the analogue, some respirable particles are expected to be present. It is expected that exposure will be minimised by various means, such as the suction created during mixing into the drilling mud, and the outdoor nature of the operations. In addition, the products containing the notified chemicals also contain hazardous ingredients and protective measures taken against these ingredients would reduce the potential for exposure of the workers to the notified chemicals. It is expected that operations will take place intermittently. Measures that would reduce the exposure potential include wearing impervious gloves, coveralls, goggles, and suitable respiratory protection. Workers should only empty bags containing the notified chemicals when facing down wind, to further reduce the potential for inhalation exposure.

Dermal contact with the notified chemicals in drilling mud at 0.4% may also occur, and would be minimised by

the use of suitable personal protective equipment (PPE).

Provided the above controls are adhered to at the end-use sites, the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

As the public are not expected to be exposed to the notified chemicals, the risk to public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemicals will be imported as a component of a finished end-use product and will not be reformulated in Australia. Therefore, no environmental release is expected from manufacture or reformulation in Australia. Release from residue in bags will be minimal (1%; up to 1,500 kg per annum) as the product is a dry powder and residues are expected to be disposed of to landfill. Accidental spills of the product are expected to be swept up and the product recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The notifier has indicated that up to 2.5 tonnes of the notified chemicals will be added to drilling muds for each well that is drilled. During gas and oil well drilling operations, drilling mud containing 0.4% w/w of the notified chemicals will be pumped down the drill shaft where it functions as a combination of lubricant for the drill bit, carrier for the solid cuttings, and sealant to minimise drilling fluid loss into the formations 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 chemicals will be recovered and then replenished with additional mud containing more notified chemicals and then transferred back down into the well. The drill cuttings that represent about 5 - 10% of the material transferred to the surface contain some adhered drilling mud. After separation, the notifier indicates that 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% (2,500 × 5% = 125 kg) of the notified chemicals that are used in drilling mud for each well 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 chemicals will be discharged into lined reserve 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 chemicals will be discharged into the ocean. For the purposes of assessment, it is assumed that all of the notified chemicals that are not released with the drill cuttings (2,375 kg = 2,500 × 95%, per well) will be subsequently discharged along with the used mud. For on-shore sites, all of the notified chemicals associated with drill cuttings and drilling muds will be discharged into the lined reserve 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 chemicals are not readily biodegradable in seawater, based on the biodegradability result attained for the analogue. The analogue is considered similar to the notified chemicals. Therefore, it is considered to be scientifically reasonable to predict the environmental fate for the notified chemicals using the analogue data. For the details of the environmental fate study conducted on the analogue, please refer to Appendix C.

The water soluble components of the notified chemicals are not expected to adsorb strongly to solids. Hence, the fate of the notified chemicals discharged into seawater in the vicinity of off-shore oil- and gas-production sites will be determined principally by the water solubility of the various components of the chemicals. The

readily water soluble components of the notified chemicals are expected to be dispersed by tidal and ocean currents following mixing of the waste drilling muds and cuttings with seawater around the discharge point. These water soluble components are expected to remain dissolved in seawater until they are degraded by abiotic processes. The water insoluble components of the notified chemicals are 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. In this matrix, degradation due to abiotic and biotic processes can be expected to be very slow considering the conditions in the piles of drill cuttings and mud, including low temperatures and low density of bacteria.

The water soluble components of the notified chemicals are not expected to bioaccumulate based on the low estimated water-octanol partition coefficients of the analogue. The water insoluble components of the notified chemicals are also not expected to bioaccumulate based on their ionised form in the environmental pH range and the relatively high molecular weights of the molecular constituents of these components.

7.1.3. Predicted Environmental Concentration (PEC)

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

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

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

In this relationship, $PEC_{water,batch}$ is related to the amount of chemicals discharged (M/ kg), the volume of mud discharged for the specific section drilled (V_m/ m^3), and the dilution factor for batch-wise discharges (D_{batch}). The specific values for volume of mud discharged and the dilution factor have not been provided for operations under Australian conditions. Hence, the default values for V_m (375 m^3 for a 1,500 m drill length) and D_{batch} (7.7×10^{-5}) as specified in the CHARM model for the batch-wise discharge scenario have been used for this calculation (Thatcher et al., 2005, p. 46). Based on these default values, and the worst case discharge of 2,375 kg of notified chemicals in a single batch of used mud, the $PEC_{water,batch}$ for the notified chemicals is calculated to be 0.49 mg/L ($PEC_{water,batch} = 2{,}375 \div 375 \times 7.7 \times 10^{-5} \times 10^3$).

The $PEC_{water,batch}$ calculated above is based on a theoretical worst-case in which all of the mass of notified chemicals discharged with a batch of mud is present in seawater within a radius of 500 m from the discharge point. However, based on the apparent insolubility of at least 50% by weight of notified chemicals in water, a significant fraction of the discharged mass of these chemicals is expected to remain associated with the insoluble minerals and other solids discharged overboard. This fraction of the notified chemicals is therefore expected to deposit on the sea floor beneath the discharge point along with the mud and cuttings. The concentration of the notified chemicals 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 an 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.48). 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 chemicals 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 (= 0.05 m), the resulting volume of affected sediment is 39,250 m^3 (= 3.14 × 500 m × 500 m × 0.05 m). If the density of the sediment is approximately 1,200 kg/m^3 (default value), then the mass of affected sediment is 47,100 tonnes (= 39,250 m^3 × 1,200 kg/m^3 × 10^{-3}). If it is further assumed for a worst case that 50% of the discharged mass of notified chemicals, equivalent to 1,187 kg (= 2,375 kg × 50%) in a batch of used mud is deposited in this layer of sediment, then the $PEC_{sediment}$ for the notified chemicals in the benthic system is estimated to be 25.2 mg/kg (= 1,187 kg ÷ 47,100 tonnes × 10^3).

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the analogue are summarised in the table below. The analogue is considered to be similar to the notified chemicals. Therefore, it is considered to be scientifically reasonable to predict the ecotoxicity endpoints for the notified chemicals using the analogue data for the purpose of risk assessment. For full details of the studies on the analogue, refer to Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (*Scophthalmus maximus)*	LC50 (96 h) > 240 mg/L	Not harmful to fish
Daphnia Toxicity		
Arcatia tonsa	EC50 (48 h) = 380 mg/L	Not harmful to aquatic invertebrates
Mysidopsis bahia	EC50 (96 h) = 420,000 mg/L	
Acanthomysis sculpta	EC50 (96 h) = 155,000 mg/L	
Macoma nasuta	99% survival when exposed to a 1.5 cm layer of analogue	Not lethally toxic to this species
Algal Toxicity *(Skeletonema costatum)*	E_rC50 (72 h) = 390 mg/L	Not harmful to algae

Based on the above results, it is concluded that the analogue is not acutely or chronically harmful to aquatic life. On this basis, the notified chemicals are not formally classified for acute or long-term hazard under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS, United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated from the acute toxicity of the notified chemicals to the most sensitive species of fish (LC (50) > 240 mg/L) using an assessment factor of 100. The ecotoxicity endpoints of the notified chemicals are expected to be accurately estimated using the analogue data given that the analogue is considered to be similar to the notified chemicals. Moreover, the ecotoxicity data for the analogue include acute toxicity end points for each of the three trophic levels of marine ecosystems. Therefore, it is reasonable to use the assessment factor of 100 to calculate the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
EC50 (Fish)	> 240 mg/L
Assessment Factor	100
PNEC:	> 2.4 mg/L

7.3. Environmental Risk Assessment

The notified chemicals are used for a specific application in the oil and gas-drilling industry at both on- and off-shore sites in northern Australia. The environmental exposure of the notified chemicals is therefore concentrated in a few locations that are geographically dispersed around the northern margins of the continent. The main route for exposure of the environment to the notified chemicals is through the discharge of drill cuttings and used drilling muds overboard at off-shore drilling sites. Effectively, all notified chemicals used in off-shore drilling operations are expected to be discharged to the ocean at the completion of drilling.

The PEC of the notified chemicals in the vicinity of an off-shore drilling site is calculated to be 0.49 mg/L based on an extreme worst-case scenario involving discharge of a batch of used drilling mud over a short period into the ocean. The risk quotient (RQ = PEC/PNEC) for this release scenario is < 0.204, indicating that the use of the notified chemicals as proposed is not expected to cause unreasonable risk to the environment.

The deposition of up to 50% of the notified chemicals in sediments on the ocean floor beneath the discharge point following a single batch-wise discharge of used mud is expected to produce concentrations of up to 25 mg/kg of the notified chemicals in the top 5 cm of sediment in a worst case. The available data for the

toxicity of the notified chemicals to benthic invertebrates indicates that even when sediment-dwelling invertebrates are exposed to a solid layer of these chemicals for 10 days they do not suffer lethal toxic effects. This result indicates that these organisms can tolerate artificially high local levels of the notified chemicals in sediment. Hence, the relatively low levels of the notified chemicals disseminated through the top layer of sediment beneath the discharge points of off-shore oil- and gas-drilling sites are not expected to have chronic toxic effects on benthic invertebrates.

Based on the preceding analysis, the notified chemicals are not expected to have adverse effects on either pelagic or benthic biota in the immediate vicinity of off-shore oil- and gas-drilling sites following a worst-case discharge of used drilling mud. Therefore, on the basis of the PEC/PNEC ratio and the assessed use pattern, the notified chemicals are not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point > 800°C (analogue chemical)

Method	Thermal gravimetric analysis
Remarks	The analogue chemical was tested. The sample did not melt at temperatures up to 800°C. Some evaporation was observed at temperatures above 200°C and some decomposition at temperatures above 750°C.
Test Facility	Unknown

Boiling Point ~739 - 1,277°C

Method	EPIWIN
Remarks	Calculated for three representative chemical structures.
Test Facility	Unknown

Density 1,435 kg/m^3 at 20°C (analogue chemical)

Method	Le Chatelier flask method
Remarks	The analogue chemical was tested. The method was based on the difference in liquid levels before and after addition of a quantity of the chemical to the flask.
Test Facility	Unknown

Vapour Pressure $\leq 8 \times 10^{-19}$ kPa at 25°C

Method	EPIWIN
Remarks	Calculated for three representative chemical structures.
Test Facility	Unknown and IUCLID (2006)

Water Solubility ≥ 4.8% w/w at 20°C and pH 10 (analogue chemical)

Method	OECD TG 105 Water Solubility.
Remarks	The water solubility of the analogue was estimated visually and gravimetrically using a flask method. In the preliminary visual test, the analogue was observed to be only partially soluble in water at all nominal concentrations in the range 5 – 90% w/w. In the indicative gravimetric test, the analogue was shaken together with water for 47 hours at 30°C before standing for 24 hours at 20°C. The test was carried out in duplicate at two nominal test concentrations of 5 and 10% w/w at an intrinsic pH of 9.7 – 10. The analogue was observed to be incompletely dissolved in each test sample. Hence, the supernatant liquid was clarified by centrifugation prior to evaporation of the solvent to determine the mass of dissolved material. The mass of dissolved solids in the aqueous phase of the 5 and 10% w/w test solutions was 2.4 and 4.8% w/w, respectively. This is equivalent to 48.4 – 48.6% w/w of the initial mass of analogue for both nominal test concentrations. This test indicates that approximately 48.5% of the analogue is soluble in water and the solubility of these fractions is at least 4.8% w/w at 20°C and pH 10. The saturation concentration of this water soluble fraction was not determined.
Test Facility	Safepharm (2005a)

Partition Coefficient (n-octanol/water) log Pow < 0 at 20°C (water soluble components, analogue chemical)

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method. The analogue was suspended in aqueous buffer at pH 8 and filtered through a 0.45 µm syringe. The water soluble components of the analogue were not retained on the chromatographic column and they eluted as a series of poorly resolved peaks before the reference substance used to determine the column dead-time (thiourea). The partitioning coefficient for the water soluble components of the analogue is therefore an estimated upper limit.
Test Facility	Chemex Environmental International (2003)

Surface Tension 61.0 mN/m at 22°C (analogue chemical)

Method EC Council Regulation No 440/2008 A.5 Surface Tension.
Remarks Ring method was used. The concentration was 1.03 g/L. The test substance was considered not to be a surface-active material.
Test Facility Harlan (2010a)

Particle Size Analogue chemical

Method Particle size analysis (Beckman Coulter LS) – in house method

Range (μm)	*Mass (%)*
< 10.33	2.58
< 106.4	28.1
< 204.3	56.4
< 519.3	90.6

Remarks Measurements were performed on an imported product (Soltex Additive) containing the analogue chemical.
Inhalable fraction (< 100 μm) ~28%
Respirable fraction (< 10 μm) ~2.6%
Mean = 213.6μm
Test Facility Unknown (2007)

Flash Point > 620°C

Method Prugh's nomagraph (Hagopian, 1990)
Remarks The notified chemicals are estimated to flash at temperatures > 620°C. This value was estimated using the calculated boiling points (see above) and plotting roughly on Prugh's nomagraph (an estimation method for pure organic compounds containing C, H, O, S, and halogens). In addition, the notifier has stated that they do not expect the notified chemical to have a flash point.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Soltex Additive (product containing an analogue chemical)
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Distilled water
Remarks - Method	No statement of GLP.
RESULTS	
LD50	> 5,000 mg/kg bw
Remarks - Results	No animals died during the study (dose level 5,000 mg/kg bw). In the dose range study, bright red lungs were observed in the single female animal that had been dosed with 4,000 mg/kg bw, and pale adrenals in the single female animal dosed at 5,000 mg/kg bw.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Hazleton (1985a)

B.2. Acute toxicity – oral

TEST SUBSTANCE	Soltex Additive (product containing an analogue chemical)
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Distilled water
Remarks - Method	No statement of GLP.
RESULTS	
LD50	> 5,000 mg/kg bw
Remarks - Results	No animals died during the study (dose level 5,000 mg/kg bw). In the dose range study, pale adrenals were observed in males that were treated with 1000, 2000, 3000 and 5000 mg/kg bw and females treated with 2000, 4000 and 5000 mg/kg bw. Dark adrenals were observed in the male animal treated with 4,000 mg/kg bw.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Hazleton (1985b)

B.3. Irritation – skin

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	Distilled water
Observation Period	7 days
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	1.3	1	0.3	2	< 7 d**	0
Oedema	0.7	0	0	1	< 72 h	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
**Slight desquamation was observed in one animal at the 7 day observation.

Remarks - Results: Light brown discolouration of the epidermis was noted at one treated skin site at the 48 and 72 hour observations with loss of skin elasticity also noted at the 72 hour observation. Slight desquamation was noted at this treated skin site at the 7 day observation.

CONCLUSION: The tested chemical is slightly irritating to the skin.

TEST FACILITY: SafePharm (2008a)

B.4. Irritation – eye

TEST SUBSTANCE: Analogue chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 males
Observation Period: 7 days
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			
Conjunctiva: redness	0.3	0.3	1	1	< 7 d	0
Conjunctiva: chemosis	0	0	0.3	1	< 48 h	0
Conjunctiva: discharge	0	0	0.3	1	< 48 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results: Black residual test material was noted in all treated eyes at the one hour observation.

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

TEST FACILITY: SafePharm (2008b)

B.5. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE: Analogue chemical

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/Ca (CBA/CaOlaHsd)
Vehicle: Dimethyl sulfoxide
Remarks - Method: No significant protocol deviations.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/animal)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	1,554.00 ± 616.29	-
2.5	1,773.71 ± 489.31	1.14
5	1,760.30 ± 618.91	1.13
10	2,339.69 ± 834.69	1.51
Positive Control		
15	4,887.88 ± 2,159.72	3.14

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the tested chemical.

TEST FACILITY SafePharm (2008c)

B.6. Repeat dose toxicity

TEST SUBSTANCE Analogue chemical

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

Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Non-recovery males: 42 days Non-recovery females and offspring: 5 days following birth Recovery animals: 42 days dosing, 14 days recovery period Pairing of animals within each dose group (for mating): Day 15 Dose regimen: 7 days per week (except for females during littering/parturition)
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations. A preliminary fourteen day repeated dose oral range finder study was performed to determine suitable dosage levels for the main study.

RESULTS

Dose mg/kg bw/day	*Number and Sex of Animals*	*Mortality*
0	10M, 10F	0
250	10M, 10F	0
500	10M, 10F	0
1,000	10M, 10F	0
0 (recovery)	5M, 5F	0
1,000 (recovery)	5M, 5F	0

No treatment-related effects were observed in any of the following parameters: clinical observations; functional observations and performance tests; behavioural assessment; sensory reactivity assessments; bodyweight and food consumption during maturation, gestation and lactation; water consumption; haematology; necropsy and urinalysis.

Blood chemistry
Some statistically significant changes in blood chemistry parameters were observed in treated animals (mainly those treated with 1,000 mg/kg/day). Such effects were considered to be of no toxicological significance due to the absence of dose related responses, histopathological correlates, other supporting data, or similar effects in non-recovery animals.

Reproductive performance
No treatment-related effects were observed in any of the following parameters: mating performance and

fertility; gestation length; litter responses; litter size and viability; offspring growth and development; clinical signs of offspring; offspring necropsy findings; organ weights; uterine examination and histopathology.

CONCLUSION
The No Observed Effect Level (NOEL) was established as 1,000 mg/kg bw/day in this study, based on the absence of toxicologically significant changes in the measure parameters in adult treated animals, their reproduction, and the development of their offspring.

TEST FACILITY	SafePharm (2007a)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	S9 mix from Sprague-Dawley rat liver induced with phenobarbitone/β-naphthoflavone
Concentration Range in Main Test	a) With metabolic activation: 50 - 5,000 µg/plate b) Without metabolic activation: 50 - 5,000 µg/plate
Vehicle	Dimethyl sulfoxide
Remarks - Method	Some of the positive control materials chosen for use without metabolic activation were not those recommended by the OECD Test Guideline.

RESULTS

Remarks - Results	No significant increases in the frequency of revertant colonies were recorded in the presence of the test substance for any of the bacterial strains at the tested concentrations, either with or without metabolic activation. Small decreases in revertant colony frequency were noted in several of the tester strains at 5,000 µg/plate, predominantly in the presence of metabolic activation.
CONCLUSION	The tested chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (2007b)

B.8. Genotoxicity – *in vitro*

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test. EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test.
Species/Strain	Human
Cell Type/Cell Line	Blood lymphocytes
Metabolic Activation System	S9 mix from Sprague-Dawley rat liver induced with phenobarbitone/β-naphthoflavone
Vehicle	Dimethyl sulfoxide
Remarks - Method	No significant protocol deviations

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 39.06, 78.13, 156.25, 312.5*, 625*, 1250*	4 h	20 h
Test 2	0, 312.5*, 625*, 1250*, 2500*, 3750, 5000	24 h	-
Present			
Test 1	0, 39.06, 78.13, 156.25, 312.5*, 625*, 1250*	4 h	20 h
Test 2	0, 39.06, 78.13, 156.25, 312.5*, 625*, 1250*	4 h	20 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 1,250	≥ 156.25	Negative
Test 2	> 5,000	2,500	≥ 312.5	Negative
Present				
Test 1	> 5,000	> 1,250	≥ 156.25	Negative
Test 2	> 5,000	> 1,250	≥ 312.5	Negative

CONCLUSION The tested chemical was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY SafePharm (2007c)

B.9. Genotoxicity – *in vitro*

TEST SUBSTANCE Analogue chemical

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

Species/Strain	Mouse lymphoma cells
Cell Type/Cell Line	L5178Y TK+/- 3.7.2c mouse lymphoma cell line
Metabolic Activation System	S9 mix from Sprague-Dawley rat liver induced with phenobarbitone/β-naphthoflavone
Vehicle	RPMI 1640 medium without serum
Remarks - Method	No significant protocol deviations, EMS and CP were used as positive controls.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	0, 156.25, 312.5, 625, 1250, 1875, 2500	4 h	2 d	10 - 15 d
Test 2	0, 156.25, 312.5, 625, 1250, 1875, 2500	24 h	2 d	10 - 15 d
Present				
Test 1	0, 156.25, 312.5, 625, 1250, 1875, 2500	4 h	2 d	10 - 15 d
Test 2	0, 156.25, 312.5, 625, 1250, 1875, 2500	4 h	2 d	10 - 15 d

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1 (4 h expo.)	≥ 156.25	≥ 1,875	≥ 156.25	Negative
Test 2 (24 h expo.)	≥ 312.5 (24 h expo.)	≥ 1,250	≥ 156.25	Negative

Present				
Test 1 (4 h expo.)	≥ 156.25 (4 h expo.)	≥ 1,875	≥ 156.25	Negative
Test 2 (4 h expo)	-	≥ 625	≥ 156.25	Negative

Remarks - Results	No significant increases in mutant cells were seen in any of the test groups. The positive and negative controls were within historical controls, confirming the validity of the test systems.
CONCLUSION	The tested chemical was not mutagenic to mouse lymphoma cells treated *in vitro* under the conditions of the test.
TEST FACILITY	Harlan (2010b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Biodegradability in seawater

TEST SUBSTANCE	Analogue chemical
METHOD	EC Guideline "Biotic degradation in seawater: Closed Bottle Method"
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The oxygen concentration was measured electrochemically
Remarks - Method	The description of the test method and results of this study are based on summary information presented in the IUCLID data set for the notified chemical. The test medium was natural seawater taken from the Eastern Scheldt (Jacobahaven) and supplemented with nutrient stock solutions. The biodegradation of the analogue was evaluated at a single nominal test concentration of 4 mg/L. Based on the summary information supplied, the concentration of the test solution is a nominal value based on dispersion of the solid chemical in water. The nominal concentration of the reference substance (sodium acetate) used in the inoculum and toxicity control solutions was 4 mg/L. The oxygen concentration in the treatment bottles was determined after 7, 14, 21, and 28 days of incubation at 20°C in the dark.
RESULTS	
Remarks - Results	The biodegradation of the reference substance was complete within 14 days. As no other test parameters were reported, it cannot be concluded that the test was valid. However, the complete biodegradation of the reference substance within a reasonable time interval does indicate that the test medium was biologically competent and that the methodology employed was adequate to monitor biodegradation of carbon compounds. The biodegradation of was in the range 3 – 6% based on the chemical oxygen demand. The limited degradation of the analogue under the conditions of this test indicates that this chemical has a low potential for biodegradation in seawater. This conclusion is consistent with a related test summarised in the same IUCLID document which showed that there was no biodegradation of the analogue over a 56-day period in seawater when the chemical was derived from a 3.5% bentonite slurry product containing 1% of the chemical as an additive. This latter test was carried out using the same closed bottle test method and with a comparable nominal level of notified chemical as that used for the test with the analogue described above.
CONCLUSION	The analogue and, by inference, the notified chemicals are not easily biodegradable in seawater.
TEST FACILITY	IUCLID (2006)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue chemical

METHOD	OECD TG 203 Fish, Acute Toxicity Test, Modified for Salt Water Species – Semi-Static.
Species	Juvenile turbot (*Scophthalmus maximus*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Unspecified. The test medium was artificial seawater.
Analytical Monitoring	None
Remarks – Method	The test medium was standard synthetic seawater with an initial nominal salinity level of 33 parts per thousand and a pH of 8.3. The tests were carried out at 14°C with a dissolved oxygen content of ≥ 7.3 mg O_2/L. The definitive test was conducted at a nominal concentration of 240 mg/L for the test substance. The test was carried out according the test guideline above without significant deviation from the protocol.

RESULTS

Concentration mg/L Nominal (WAFs)	*Number of Fish*	*Mortality (%)*				
		3 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0	0
240	7	0	0	14*	14	14

*Single mortality was considered to be possibly due to natural cause rather than a toxic effect given that no further mortalities were observed and no sub-lethal effects of exposure were observed throughout the test.

LC50	> 240 mg/L at 96 hours.
NOEC	240 mg/L at 96 hours
Remarks – Results	The highest test concentration resulting in 0% mortality was determined to be ≥ 240 mg/L. The results were based on nominal concentration as the actual concentrations for the test substance were not determined. The no observed effect concentration was based upon zero significant mortalities and the absence of any sub-lethal effects of exposure at this concentration.
CONCLUSION	The analogue and, by inference, the notified chemicals are not harmful to fish
TEST FACILITY	Safepharm (2005b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Analogue chemical
METHOD	ISO TC147/SC5/WG2 "Water Quality, Determination of Acute Lethal Toxicity to Marine Copepods (*Copepoda, Crustacea*)"
Species	*Arcatia tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Unspecified. The test medium was artificial seawater.
Analytical Monitoring	None
Remarks - Method	The test medium was standard synthetic seawater with an initial nominal salinity level of 31 parts per thousand and a pH of 8.1. The tests were carried out in loosely covered 50 mL glass jars at 21.7 – 22.2°C with 16 hours of continuous artificial light. The test solutions were prepared as dispersions of the analogue in artificial seawater by ultra-sonication of the solid test material in the test medium. The test solutions were not filtered prior to toxicity testing and the concentration of analogue in solution was not confirmed by analysis.

These solutions were not replaced during the exposure period.

A preliminary range finding test was carried out at nominal test concentrations of 0.10, 1.0, 10, 100 and 1000 mg/L. The definitive test was carried out using 9 geometrically-spaced nominal concentrations in the range 10 – 1,000 mg/L. The 48-hour acute toxicity end-point and the associated 95% confidence interval were calculated by means of the maximum-likelihood probit method. This analysis is based on the nominal concentrations of the analogue in the test medium and the observed immobility of the copepods in the definitive test.

The sensitivity of the copepods to toxic substances was assessed with potassium dichromate at 9 geometrically-spaced nominal concentrations in the range 0.56 – 56 mg/L.

RESULTS

Concentration mg/L Nominal	*Number of A. tonsa*	*Number Immobilised*	
		24 h	*48 h*
Control	4 × 5	0	0
10	4 × 5	0	0
18	4 × 5	0	0
32	4 × 5	0	0
56	4 × 5	0	0
100	4 × 5	0	0
180	4 × 5	0	0
320	4 × 5	0	1(A), 1(B), 2(C), 2(D)*
560	4 × 5	0	5(A), 5(B), 4(C), 4(D)*
1,000	4 × 5	3(A), 2(B), 2(C), 1(D)*	20

* The descriptors (A), (B), (C), (D) refer to replicate test Vessels 1, 2, 3, and 4, respectively, which each contained 5 copepods initially.

LC50	> 1,000 mg/L at 24 hours 380 (95% CI: 330 – 440) mg/L at 48 hours
NOEC (or LOEC)	180 mg/L at 48 hours
Remarks - Results	The temperature at the end of the exposure period of the definitive test slightly exceeded the maximum recommended in the experimental protocol (22.2 *vs*. 22.0°C). However, this deviation was not considered significant as there were no mortalities in the procedural control vessels. The 48-hour LC50 for the positive control under these test conditions is 4.5 (95% CI: 3.8 – 5.5) mg/L, which is within the normal range for this reference substance. Based on these results, the test is considered valid. The initial concentrations of oxygen in the test solutions for the definitive test were significantly lower than in the controls for nominal exposure concentrations ≥ 100 mg/L. This oxygen depletion effect is dependent on the nominal concentration of the analogue and was most pronounced for the 1,000 mg/L nominal test concentration. However, the minimum oxygen concentration at test initiation was above the minimum stated in the protocol (4.4 vs. 4.0 mg O_2/L), and the average concentration of oxygen in all test vessels was ≥ 70% of the air-saturation value at the end of the exposure period. Although the origin of this effect was not explained, the oxygen concentration in all test solutions remained within acceptable limits based on the experimental protocol and this effect does not appear to have invalidated the test results. In the preliminary test, no mortalities were observed at nominal test

concentrations ≤ 100 mg/L, but mortalities were observed at the highest nominal concentration of 1,000 mg/L. At the two highest nominal test concentrations there was significant turbidity in the test solutions arising from the water insoluble components of the analogue. A microscopic examination of dead copepods revealed that test material had adhered to the carapaces of these animals. This was attributed to post-mortem contact between dead copepods and a layer of notified chemical sediment at the bottom of the test vessel and is not considered to reflect evidence of physical toxic effects of the suspended material on the test organisms.

In the definitive test, all test solutions with nominal concentrations of analogue in the range 18 – 1,000 mg/L were turbid and the turbidity increased with increasing nominal concentration. However, microscopic analysis of dead copepods from these test vessels indicated that these mortalities were not related to physical toxicity effects because there was no analogue adhered to the carapaces, antennae or thoracic appendage of these organisms.

The 48-hour NOEC value is based solely on the absence of mortality among copepods in the test vessels as no observation of non-lethal toxic effects were made.

The calculated 48-hour LC50 (= 380 × 40% = 152 mg/L) for the analogue based on nominal concentrations and estimated solubility is greater than the 100 mg/L, indicating that the analogue is not harmful to aquatic invertebrates.

Additional Related Studies from IUCLID

The conclusions of this study are consistent with three additional studies of the toxicity of the analogue with other marine invertebrates summarised in the IUCLID document for this chemical (IUCLID 2006). These studies include two 96-hour acute toxicity tests of the analogue with *Mysidopsis bahia* and *Acanthomysis sculpta*, and a third semi-quantitative 10-day chronic toxicity test with the sediment-dwelling bivalve, *Macoma nasuta*.

The toxicity test with mysid shrimp was conducted according to EPA 40 CFR Part 435 on the water accommodated fraction of the analogue in aged, filtered, and aerated synthetic seawater. The test substance was derived from a drilling fluid containing the analogue, but the concentration of chemical in this product was not reported. The toxicity of the positive control substance (sodium lauryl sulfate) was 8.5 (95% CI: 8.0–9.1) mg/L under the conditions of the test. The 96-hour LC50 for the analogue with *Mysidopsis bahia* based on nominal WAF loading levels is 420,000 (95% CI: 368,000 – 481,000) mg/L.

The toxicity test for the analogue with the temperate water mysid, *Acanthomysis sculpta*, was carried out according to the EPA Region 2 Drilling Mud Bioassay method on the water accommodated fraction of this chemical in filtered natural seawater. The test substance was derived from a drilling mud containing the notified chemical, but the concentration of chemical in this product was not reported. The 96-hour LC50 for the analogue with *Acanthomysis sculpta* is 155,000 mg/L based on the results of a liquid phase bioassay of the test medium and 205,000 mg/L based on a suspended particulate phase bioassay.

The semi-quantitative chronic toxicity test of the analogue with *Macoma nasuta* was also carried out according to the EPA Region 2 Drilling Mud Bioassay method using the same drilling mud used for the acute toxicity test for *A. sculpta*. In this case, the drilling mud was washed and settled in

filtered natural seawater and the settled residue was used to provide a 1.5 cm layer of drilling mud over a 3 cm deep layer of control mud containing the sediment-dwelling bivalves (20 per tank). The overlying seawater in the test tanks was constantly replenished by a flow-through seawater system over the 10-day test period. The numbers of surviving bivalves were counted at the end of the exposure period and this analysis indicated that there was one mortality in the 5 replicate test chambers (1 animal in 100) and no mortalities in the 5 replicate control chambers. Based on this test, drilling mud containing the analogue is not lethally toxic to *Macoma nasuta*.

CONCLUSION The analogue and, by inference, the notified chemicals are not harmful to invertebrates.

TEST FACILITY Safepharm Laboratories (2005c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Analogue chemical

METHOD ISO Guideline No 10253 "Water Quality – Marine Alga Growth Inhibition Test with *Skeletonema costatum* and *Phaeodaclytum tricornutum*"

Species	*Skeletonema costatum*
Exposure Period	72 hours
Concentration Range	Nominal: 62.5, 125, 250, 500 and 1000 mg/L Actual: Not determined
Auxiliary Solvent	None
Water Hardness	Unspecified. The test medium was nutrient supplemented natural seawater.
Analytical Monitoring	None

Remarks - Method

The culture medium for this test was natural seawater sterilised by filtration and supplemented with a standard array of trace elements, macronutrients and vitamins. The pH of the culture medium was adjusted to 8.0 ± 0.2 for testing. The tests were carried out in plugged 250 mL glass flasks on a test volume of 100 mL at 20 ± 1°C. The flasks were continuously irradiated and constantly shaken for the full 72-hour exposure period.

The density of algae in the test flasks was determined using a haemocytometer and light microscope. These measurements were made at the 0-, 24-, 48- and 72-hour time-points. The nominal cell density at test initiation was 10^4 cells per mL.

The test solutions were prepared as dispersions of the analogue in artificial seawater by the same method as that used for the acute toxicity test with *A. tonsa*. As for the invertebrate toxicity test, the algal test solutions were not replaced during the exposure period.

A preliminary range-finding toxicity test was carried out at nominal test concentrations of 0.1, 1.0, 10, 100, and 1000 mg/L.

The rate of algal growth in the definitive toxicity test was based on the mean growth rates determined from three replicates at each test concentration. The statistical analysis of the area under the growth curve in these definitive tests was carried out by means of Bartlett's test for homogeneity of variance and Dunnett's multiple comparison procedure. The 95% confidence intervals in the toxicity end-points were calculated by the method of Litchfield and Wilcoxon.

The sensitivity of the test system to toxic substances was evaluated with

potassium dichromate at nominal concentrations of 0.313, 0.625, 1.25, 2.5, and 5.0 mg/L.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOEC mg/L*	*E_rC50 mg/L at 72 h*	*NOEC mg/L*
240 (95% CI: 220 – 260)	125	390 (95% CI: 350 – 430)	125

Remarks - Results

The cell densities in the controls increased by a factor of 71 in the definitive test, which is greater than the 16-fold increase required for test validity. The physico-chemical parameters were stable and remained within the specified limits, and the 72-hour E_rC50 for the positive control (2.5 mg/L, 95% CI: 1.5 – 4.3) was within the normal range for this substance as specified in the Test Guideline. The only significant deviation from the test protocol was the failure to execute a regrowth study after the 72-hour exposure period as required for coloured test materials. However, separate spectrophotometric measurements of the absorption of light in the test medium were carried out at the photosynthetically important wavelengths of 460 and 665 nm. This was sufficient to indicate that significant absorption of light at these wavelengths was the probable cause of the growth rate inhibition in the test solutions (see below) and that a regrowth test was not essential. Hence, the study is considered valid.

The preliminary range finding test indicated that the growth of algae was inhibited at the highest nominal test concentration of 1,000 mg/L. The percent inhibition in growth relative to controls at this concentration was 79%.

In the definitive test, statistically significant differences in the growth of algae between controls and treatment groups were found for nominal analogue concentrations ≥ 250 mg/L. The NOEC for algal growth is based on this analysis and no separate calculation of the NOEC for the inhibition of biomass and growth rate was performed.

In the definitive test, the inhibition of biomass and growth rate at the highest nominal test concentration was 102% and 97%, respectively, after 72 hours. However, the test solutions for this nominal test concentration were observed to be black brown dispersions. A spectrophotometric analysis of the 1,000 mg/L test solution showed essentially complete absorption of incident light at the photosynthetically important wavelengths of 460 and 665 nm. Also, observations of cells taken from the 1,000 mg/L test solution after the 72-hour exposure period revealed the presence of misshapen cells. Taken together, these results indicate that the algal toxicity end-points derived for the analogue in this study reflect a reduction in light intensity in the test medium rather than a chemical toxicity effect of the chemical. Based on this analysis, the EC50 for chemo-toxic effects of the analogue must be greater than 240 mg/L, which is above the 100 mg/L threshold figure indicated as harmful to algae under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations 2003). Therefore, the analogue is classified as not harmful to algae.

Additional Related Study from IUCLID

The toxicity of the analogue to *Skeletonema costatum* was also evaluated in an earlier study that is summarised in the IUCLID document for this chemical (IUCLID 2006). This test was carried out using a similar

	experimental method to that used for the more recent algal toxicity test, except that cell growth was monitored by the Coulter particle-counting method and the test period was extended to 95 hours. Based on the results of this test, the EC50 with respect to inoculum viability followed by logistic growth (E_eC50) was found to be 4.0 g/L of a nominal 1% solution of the chemical in water. This is equivalent to an E_eC50 of 40 mg/L for the analogue, which nominally indicates that the chemical may be classified as harmful to marine algae. However, this earlier test did not account for the inner-filter effect of the analogue and the resulting physical inhibition of the growth of algae exposed to this chemical. Also, the Coulter method is apparently less accurate than microscopically based cell counting methods for *Skeletonema costatum* (Safepharm Laboratories, 2005c). Hence, the results from this earlier algal toxicity test are not considered indicative of the chemo-toxicity of the analogue and have not been included in the environmental risk assessment.
CONCLUSION	The analogue and, by inference, the notified chemicals are not harmful to algae.
TEST FACILITY	Safepharm Laboratories (2005d)

BIBLIOGRAPHY

Barratt MD, Basketter DA, Chamberlain M, Admans GD and Langowski JJ (1994), An Expert System Rulebase for Identifying Contact Allergens. Toxicology In Vitro 8(5), 1053-1060

Chemex Environmental International (2002) The Toxicity to Turbot (*Scophthalmus maximus*) of Soltex Additive, Chemex reference: ENV6103/050221. Chemex Environmental International Limited, Cambridge, England (Unpublished report provided by notifier).

Chemex Environmental International (2003) The Bioaccumulation Potential of the *Analogue Chemical*, Chemex reference: ENV6222/100202. Chemex Environmental International Limited, Cambridge, England (Unpublished report provided by notifier).

CICAD (2004) Concise International Chemical Assessment Document 59: Asphalt (Bitumen), World Health Organisation, Geneva, Switzerland, Document 59.

Hagopian JH (1990) Flash Points of Pure Substances In: Lyman WJ, Reehl WF, Rosenblatt DH, ed. Handbook of Chemical Property Estimation Methods: Environmental Behaviour of Organic Compounds, McGraw-Hill Book Co., New York

Harlan (2010a) Analogue chemical: Determination of Surface Tension (Project Number 1635/0079, April 2010), Shardlow, UK, Harlan Laboratories Ltd (Unpublished report provided by notifier).

Harlan (2010b) Analogue chemical: L5178Y TK +/- Mouse Lymphoma Assay (Project Number 1635/0080, June 2010), Shardlow, UK, Harlan Laboratories Ltd (Unpublished report provided by notifier).

Hazleton (1985a) Acute Oral Toxicity Study in Rats Product #5, Project Number 2375-104. Hazleton Laboratories America Inc, Virginia, USA (Unpublished report provided by notifier).

Hazleton (1985b) Acute Oral Toxicity Study in Rats Product #2, Project Number 2375-101. Hazleton Laboratories America Inc, Virginia, USA (Unpublished report provided by notifier).

Heritage Research Group (2012) Implications of IARC Monograph 103 for the Asphalt Emulsion Industry, Anthony Kriech, International Symposium on Asphalt Emulsion Technology, October 2012.

HPV (2006) High Production Volume (HPV) Chemical Challenge Program Revised Test Plan Asphalt Category.

Hulzebos E, Maslankiewicz L, Walker JD (2003), Verification of literature-derived SARs for skin irritation and corrosion. QSAR & Combinatorial Science 22, 351-363

Hulzebos E, Walker JD, Gerner I and Schlegel K (2005), Use of Structural Alerts to Develop Rules for Identifying Chemical Substances with Skin Irritation or Skin Corrosion Potential. QSAR & Combinatorial Science 24, 332-342

IARC (1987) International Agency for Research on Cancer – Summaries & Evaluations, International Agency for Research on Cancer, Lyon, France, p 133 (IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Supplement 7).

IUCLID (2006) International Uniform Chemical Information Database: *Notified Chemical* (Data set provided by notifier).

Klassen (1996) Casarett and Doulls Toxicology: The Basic Science of Poisons, McGraw Hill, New York, pg 448

Lauby-Secretan et al (2011) Bitumens and bitumen emissions, and some heterocyclic polycyclic aromatic hydrocarbons, The Lancet Oncology, 2011, 12(13), 1190-1191.

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.

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 12 May 2013.

Safepharm (2005a) *Analogue chemical*: Determination of Water Solubility, (SPL Project Number 1635/034. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2005b) *Analogue chemical*: Acute toxicity to Juvenille Turbot (*Scophthalmus maximus) (*SPL project No. 1635/0066 September 2008) Safepharm Laboratories Limited, Chevron Phillips chemical Co. LP, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2005c) *Analogue chemical*: Acute toxicity to *Acartia Tonsa*, ISO Guideline TC147/SC5/WG2, SPL Project Number 1635/032. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2005d) *Analogue chemical*: Marine Algal Inhibition Test, SPL Project Number 1635/033. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2007a) *Analogue chemical*: Oral (Gavage) Combined Repeat Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test in the Rat, SPL Project Number 1635/043. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2007b) *Analogue chemical*: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium* and *Escherichia coli*, SPL Project Number 1635/0053. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2007c) *Analogue chemical*: Chromosome Aberration Test in Human Lymphocytes *in vitro*, SPL Project Number 1635/0052. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2008a) *Analogue chemical*: Acute Dermal Irritation in the Rabbit, SPL Project Number 1635/0057. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2008b) *Analogue chemical*: Acute Eye Irritation in the Rabbit, SPL Project Number 1635/0058. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

Safepharm (2008c) *Analogue chemical*: Local Lymph Node Assay in the Mouse, SPL Project Number 1635/0059. Safepharm Laboratories Limited, Derby, Derbyshire, UK (Unpublished report provided by notifier).

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

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 >.