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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in Soltex® Additive

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:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chevron Phillips Chemicals Australia Pty Ltd (ABN: 29 107 015 896)
Suite 409; 685 Burke Road
Camberwell VIC 3124

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name; Other Names; CAS Number; Molecular and Structural Formulae and Molecular Weight of representative components of notified chemical

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Flash point; Flammability; Autoignition temperature; Explosive properties; Acute dermal toxicity; Acute inhalation toxicity.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
The notified chemical is listed on the following chemical inventories:
Toxic Substances Control Act Inventory (TSCA)
Canadian Domestic Substances List (DSL)
European Inventory of Existing Commercial Chemical Substances (EINECS)
Korean Existing Chemicals List (ECL)
Philippines Inventory of Chemicals and Chemical Substances (PICCS)
ASIA-PAC – Collection of inventories/lists from countries in the Asia-Pacific region
New Zealand Inventory of Chemicals (NZIoC)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Soltex® Additive (product containing 60-85% notified chemical)

MOLECULAR WEIGHT
300-5000 Da, based on the molecular weights of the components of asphalt.

ANALYTICAL DATA
Reference NMR, IR, HPLC, GC, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 100%

CHEMICAL COMPOSITION
The notified chemical is an asphalt derivative (that is, the asphalt has been reacted to result in a change to its chemical composition). Three chemical structures are considered to be representative of the constituents of the notified chemical and have been used by the notifier for determination of several properties of the notified

chemical. However, the chemical composition of the notified chemical is highly dependent upon the asphalt used to produce it. 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 the cracked crude oil. The notifier has stated that the use of the same grade of asphalt for synthesis of the notified chemical 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 weight% carbon, 7-13 weight% hydrogen, up to 3 weight% nitrogen, up to 8 weight% sulfur, up to 8 weight% 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 2000–5000.
b) Resins (15-25% by weight of asphalt): heterogeneous polar aromatic compounds with small amounts of oxygen, nitrogen and sulfur. Molecular weight typically 800-2000.
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 500-1000.

The majority of these groups are likely to be present in the notified chemical (asphalt derivative). Three structures that are considered to be representative of the constituents of the notified chemical (in terms of chain length and substitutions from the chain) have been used for calculation of some properties of the notified chemical.

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/Freezing Point	>800°C	Measured
Boiling Point	~739 – 1277 °C	Calculated
Density	1435 kg/m^3 at 25°C	Measured
Vapour Pressure	Involatile	Calculated
Water Solubility	≥ 4.8% w/w at 20°C and pH 10	Estimated
Hydrolysis as a Function of pH	Not expected to hydrolyse under environmental pH conditions	Based on the structure of the notified chemical
Partition Coefficient (n-octanol/water)	log P_{ow} < 0 at 20°C	Estimated for the water soluble components of the notified chemical
Adsorption/Desorption	Water soluble components are not expected to adsorb to sediment	Based on the ready water solubility and structure of some components of the notified chemical
Dissociation Constant	Ionised over the full environmental pH range	Based on the functional group chemistry of the notified chemical
Particle Size	Inhalable fraction (<100 μm): ~28% Respirable fraction (<10 μm): ~2.6%	Measured
Flash Point	>620°C	Estimated/Calculated
Flammability	Not determined	Not expected to be flammable under normal conditions of use.

Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	See Discussion below

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please 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 chemical. Therefore, the notified chemical is not expected to exhibit explosive properties.

Reactivity
The notified chemical is stable under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as a component of a product (Soltex Additive) at concentrations of 60-85%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	~85	~85	~85	~85	~85

PORT OF ENTRY
Adelaide, Darwin, Dampier, Fremantle, Broome, Melbourne, Brisbane

IDENTITY OF RECIPIENTS
The product containing the notified chemical will be supplied to drilling fluids service companies such as M-I Swaco, Halliburton, Rheochem, Australian Mud Co., Baker Hughes Drilling Fluids, etc. It will then be sold to end user companies such as Chevron, ConocoPhillips, Woodside, Santos, Apache, Inpex, etc.

TRANSPORTATION AND PACKAGING
The product containing the notified chemical will be imported in polyethylene lined paper bags (11.3 or 22.6kg). 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 chemical will be used as a component of a shale/well formation stabiliser in drilling muds during on-shore and off-shore oil and gas well drilling operations. It is used for maintaining the integrity of the formation of the well during drilling operations. The majority of off-shore drilling will occur in the Northern Territory and possibly the North West shelf of Western Australia.

OPERATION DESCRIPTION
It is estimated that approximately 2.5 tonnes of the notified chemical 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 import bags containing Soltex Additive (60-85% notified chemical) 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 Soltex Additive product from the hopper by the Venturi effect and mixes the Soltex Additive product into the drilling mud (notified chemical 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 product enters the delivery pipe.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
Dermal, ocular and inhalation exposure of workers to the notified chemical (at concentrations up to 85%) may occur during emptying of the Soltex Additive product into the hopper. 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 product. In addition, such operations will be performed in well ventilated areas and it is expected that workers will wear skin and eye protection, further reducing exposure to the notified chemical.

6.1.2. Public exposure
The public are not likely to be exposed to the notified chemical as it will only be used by workers in the drilling industry.

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	low oral toxicity LD50 >5000 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 1000 mg/kg/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro mammalian chromosome aberration test	non genotoxic

The toxicological investigations summarised above were performed on different batches of the notified 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 chemical.

Toxicokinetics, Metabolism and Distribution
It is noted that the notified chemical is a complex mixture and as such, its pharmacokinetic behaviour will be dependent on the properties of the individual constituents. As such it is considered to be inappropriate to generalise concerning the extent of its absorption, distribution and metabolism. The below statements regarding the expected behaviour of the notified chemical are based upon the properties of the bulk material, however, it is noted that the presence of levels of chemical species (expected to be low) for which such predictions are not valid cannot be ruled out.

The notified chemical is not expected to be absorbed dermally based on its expected 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 notified chemical (in the acute oral toxicity study and repeat dose oral toxicity study) suggest that absorption from the gastrointestinal tract is minimal. This is further supported by predictions on the basis of the high molecular weight and low water solubility of the notified chemical.

No data was submitted on the inhalation toxicity of the notified chemical. There is potential for inhalation of the notified chemical, given the significant proportion that is of inhalable size (inhalable fraction (<100 μm): ~28%). However, following inhalation, the majority of the notified chemical is expected to be deposited in the nose or oral pharynx and would be unable to penetrate tissues due to the small amount portion of respirable particles (~2.6%) (Klassen, 1996). The smaller particles may eventually be coughed or sneezed out of the body, cleared from the lungs, a small amount may be transported to the blood, 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.

Acute Toxicity
The notified chemical was found to be of low acute oral toxicity in rats (LD50 >5000 mg/kg bw) based on two separate studies performed on different batches.

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

Irritation and Sensitisation
The notified chemical 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 chemical is likely to contain a number of structural moieties that are known to be 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, resulting in an NOEL of 1000 mg/kg/day. This study also examined effects on reproduction/development, resulting in no significant toxicological observations and an NOEL of 1000 mg/kg/day.

Mutagenicity
The notified chemical produced negative results in the two in vitro mutagenicity/genotoxicity tests performed.

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 chemical 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).

Studies performed on structurally similar chemicals indicated that the notified chemical is unlikely to be genotoxic (HPV, 2006). It is noted that asphalt is classified by the IARC as a Category 3 carcinogen (not classifiable as to its carcinogenicity in humans) (IARC, 1987).

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.

Classification
Based on the available data the notified chemical cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
As a worst case, some exposure of workers to the notified chemical (concentrations up to 85%) may occur during emptying of the product into the hopper (dermal, ocular and inhalation). Inhalation is unlikely to be of significant concern, given that only a small proportion is of respirable size. It is expected that exposure will be lowered by various means, such as the suction created during mixing into the drilling mud, and the outdoor nature of the operations. In addition, it is expected that operations will take place intermittently. It is recommended that measures be taken to further minimise the potential for exposure of workers to the notified

chemical, such as the wearing of gloves, coveralls, goggles, and a face mask. In addition, workers should only empty bags containing the notified chemical when facing down wind. Given that testing on the notified chemical suggests that it is of low hazard and exposure is expected to be low, the notified chemical is not considered to pose an unacceptable risk to workers.

6.3.2. Public health

As the public are not expected to be exposed to the notified chemical, the risk to public health is considered 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 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%; 850 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 2000 kg of the notified chemical (2.4% of the import quantity) 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 chemical 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 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% 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% of the notified chemical that is used in drilling mud for each well (100 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 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 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 1900 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 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 chemical is not readily biodegradable in seawater and the water soluble components are not expected to adsorb strongly to solids. Hence, the fate of the notified chemical 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 chemical. The readily water soluble components of the notified chemical 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 chemical 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 notified chemical is not expected to bioaccumulate in pelagic or benthic biota.

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

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 chemical in seawater in the vicinity of off-shore drilling sites than the continuous discharge of drilling muds entrained in cuttings.

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

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

In this relationship, $PEC_{water,batch}$ is related to the amount of chemical discharged (M/ kg), the volume of mud discharged for the specific section drilled (V_m/ m^3), and the dilution factor for batch-wise discharges (D_{batch}). The 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 1500 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 1900 kg of notified chemical in a single batch of used mud, the $PEC_{water,batch}$ for the notified chemical is calculated to be 0.39 mg/L.

The $PEC_{water,batch}$ calculated above is based on a theoretical worst-case in which all of the mass of notified chemical discharged with a batch of mud is present in seawater within a radius of 500 m from the discharge point. However, based on the apparent insolubility of at least 50% by weight of notified chemical in water, a significant fraction of the discharged mass of this chemical is expected to remain associated with the insoluble minerals and other solids discharged overboard. This fraction of the notified chemical is therefore expected to deposit on the sea floor beneath the discharge point along with the mud and cuttings. The concentration of the notified chemical in sediment ($PEC_{sediment}$) is therefore of potential significance.

The $PEC_{sediment}$ for a batch-wise discharge scenario is not calculated in the CHARM model because there is assumed to be insufficient time to allow the establishment of 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. 73). This scenario cannot be evaluated for Australia as the specific model parameters are not available and the default values for some key parameters are specific to drilling operations in the North Sea. However, an estimate of the $PEC_{sediment}$ can be made in accordance with the CHARM model assuming that the greatest effect of the chemical will occur within a radius (r) of 500 m from the discharge line. In this case, the total volume of sediment affected is $\pi r^2 d$. If the depth of sediment (d) is taken to be 5 cm, the resulting volume of affected sediment is 39 270 m^3. If the density of the sediment is approximately 1200 kg/m^3 (default value), then the mass of affected sediment is 47 100 tonnes. If it is further assumed for a worst case that 50% of the discharged mass of notified chemical in a batch of used mud (950 kg) is deposited in this layer of sediment, then the $PEC_{sediment}$ for the notified chemical in the benthic system is estimated to be 20.2 mg/kg.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity		
Scophthalmus maximus (96 hours)	LC50 1672 mg/L	Not harmful
Invertebrate Toxicity		
Arcatia tonsa (48 hours)	EC50 380 mg/L	Not harmful
Mysidopsis bahia (96 hours)	EC50 420,000 mg/L	Not harmful
Acanthomysis sculpta (96 hours)	EC50 155,000 mg/L	Not harmful
Macoma nasuta (10 days)	99% survival when exposed to a 1.5 cm layer of notified chemical	Not lethally toxic to this species
Algal Toxicity		
Skeletonema costatum (72 hours)	E_rC50 390 mg/L	Not harmful

Based on the indicated toxicity to the marine copepod, *Arcatia tonsa*, marine invertebrates are the most sensitive biota to toxic effects of the notified chemical. However, the acute toxicity end-point for *A. tonsa* is significantly above the 100 mg/L threshold for formal classification as harmful to invertebrates. The 72-hour test result for *Skeletonema costatum* nominally indicates that this marine diatom has comparable sensitivity to the notified chemical as *A. tonsa*. However, this end-point reflects the results of physical inhibition of the growth of the diatoms by suspended notified chemical and does not reflect the chemical toxicity of the notified chemical. In a real environmental release scenario, the physical toxicity of the notified chemical to algae is expected to be overwhelmed by the effects of the mineral particles in drilling muds, of which the notified chemical is a minor component.

The toxicity of the notified chemical to benthic invertebrates has been evaluated with a single species (*Macoma nasuta*) in a semi-quantitative chronic toxicity test. The results of this test, which was conducted under conditions replicating exposure to a concentrated quantity of drilling mud deposited on top of sediment, indicate that the notified chemical has no significant toxic effects on sediment dwelling bivalves over a 10-day exposure period. Based on this single result, the notified chemical is not lethally toxic to benthic invertebrates.

7.2.1 Predicted No-Effect Concentration

The available ecotoxicity data for the notified chemical include acute toxicity end points for each of the three trophic levels of marine ecosystems. However, there are no adequate chronic toxicity end-points for fish and invertebrates. Therefore, the Predicted No-Effect Concentration (PNEC) was calculated from the acute toxicity of the notified chemical to marine invertebrates using an assessment factor of 100.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Marine Invertebrate)	380	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	380	µg/L

7.3. Environmental risk assessment

The notified chemical is 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 chemical 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 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 PEC of the notified chemical in the vicinity of an off-shore drilling site is calculated to be 0.39 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 1.0, which nominally indicates that the use of this notified chemical may have the potential to have an adverse effect on pelagic biota within a

radius of 500 m of the release point. However, this calculation does not include the likelihood that the bio-available concentration of notified chemical in the water column following release of used mud will be significantly reduced by the insolubility of approximately 50% of the chemical in water. For example, if ≥ 50% of the notified chemical is removed from the water column along with the mineral particles in mud and drill cuttings by sedimentation to the ocean floor, the PEC for this chemical is expected to be ≤ 50% of the worst-case value, or ≤ 0.20 mg/L. In this scenario, the RQ for pelagic biota is ≤ 0.53 (= (≤ 0.20)/0.38), which indicates that there should be no adverse effect on these biota following a batch-wise release of used mud. Furthermore, sensitive biota in the vicinity of the discharge point are only likely to be exposed to peak concentrations of the notified chemical for a short period following discharge of the mud before the combined actions of tidal and ocean currents act to disperse the soluble components of the chemical to well below potentially toxic levels.

The deposition of up to 50% of the notified chemical 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 20 mg/kg of this chemical in the top 5 cm of sediment in a worst case. The available data for the toxicity of the notified chemical to benthic invertebrates indicates that even when sediment-dwelling invertebrates are exposed to a solid layer of this chemical 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 chemical in sediment. Hence, the relatively low levels of the notified chemical 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 chemical is 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. 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 cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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.

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations
CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Perform under well-ventilated conditions.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Avoid contact with eyes and skin.
  - Avoid inhalation of dust.
  - Only empty bags outdoors when facing down wind.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Gloves, safety glasses, coveralls.
  - Respiratory protection during outdoor operations.

  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.

Environment

- The notified chemical should be disposed of by landfill.
- 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 a component of a shale/well formation stabiliser in drilling muds for on-shore and off-shore oil and gas drilling operations, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 85 tonnes per annum, or is likely to increase, significantly;
  - if the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

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

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of products containing 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

Melting Point >800ºC

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

Boiling Point ~739 – 1277 ºC

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

Density 1435 kg/m^3 at 20ºC

Method Le Chatelier flask method
Remarks This method is based on the difference in liquid levels before and after addition of a quantity of notified chemical to the flask.
Test Facility Unknown

Vapour Pressure ≤ $8x10^{-19}$ kPa at 25ºC

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

Water Solubility ≥4.8% w/w at 20ºC and pH 10

Method OECD TG 105 Water Solubility.
Remarks The water solubility of the notified chemical was estimated visually and gravimetrically using a flask method. In the preliminary visual test, the notified chemical 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 notified chemical 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 notified chemical 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 notified chemical for both nominal test concentrations. This test indicates that approximately 48.5% of the notified chemical 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)

Hydrolysis as a Function of pH Hydrolytically stable in the environmental pH range (4–9)

Remarks The structure of the chemical constituents of the notified chemical and the method of manufacture both indicate that this chemical is unlikely to undergo hydrolysis in the environmental pH range (4–9).

Partition Coefficient (n-octanol/water) log P_{ow} < 0 at 20ºC (water soluble components)

Method OECD TG 117 Partition Coefficient (n-octanol/water), High Performance Liquid Chromatography (HPLC) Method.

Remarks The notified chemical was suspended in aqueous buffer at pH 8 and filtered through a 0.45 μm syringe. The water soluble components of the notified chemical 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 notified chemical is therefore an estimated upper limit.
Test Facility Chemex Environmental International (2003)

Adsorption/Desorption Not determined

Remarks The water soluble components of the notified chemical are not expected to partition to sediment or suspended organic matter based on their ready solubility in water. The water insoluble components of the notified chemical are expected to dissipate from the water column by a combination of flocculation and sedimentation.

Dissociation Constant Ionised over the full environmental pH range (4–9)

Remarks The functional group chemistry of the notified chemical indicates that it will be partly or fully dissociated over the entire environmentally relevant pH range.

Particle Size

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 the imported product (Soltex Additive) rather than on the notified 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 chemical is 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 (product containing notified 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	>5000 mg/kg bw
Remarks - Results	No animals died during the study (dose level 5000 mg/kg bw). In the dose range study, bright red lungs were observed in the single female animal that had been dosed with 4000 mg/kg bw, and pale adrenals in the single female animal dosed at 5000 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Hazleton (1985a)

B.2. Acute toxicity – oral

TEST SUBSTANCE	Soltex (product containing notified 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	>5000 mg/kg bw
Remarks - Results	No animals died during the study (dose level 5000 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 4000 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Hazleton (1985b)

B.3. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Vehicle	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 days**	0
Oedema	0.7	0	0	1	<72 hr	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 notified chemical is slightly irritating to the skin.
TEST FACILITY	SafePharm (2008a)

B.4. Irritation – eye

TEST SUBSTANCE	Notified 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 days	0
Conjunctiva: chemosis	0	0	0.3	1	< 48 hr	0
Conjunctiva: discharge	0	0	0.3	1	< 48 hr	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 notified chemical is slightly irritating to the eye.
TEST FACILITY	SafePharm (2008b)

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

TEST SUBSTANCE	Notified 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)	1554.00 ± 616.29	-
2.5	1773.71 ± 489.31	1.14
5	1760.30 ± 618.91	1.13
10	2339.69 ± 834.69	1.51
Positive Control		
15	4887.88 ± 2159.72	3.14

CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	SafePharm (2008c)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test.
Species/Strain	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
1000	10M, 10F	0
0 (recovery)	5M, 5F	0
1000 (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 1000 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 1000 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	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, 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 - 5000 µg/plate b) Without metabolic activation: 50 - 5000 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 notified chemical 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 5000 µg/plate, predominantly in the presence of metabolic activation.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	SafePharm (2007b)

B.8. Genotoxicity – in vitro

TEST SUBSTANCE	Notified 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 hr	20 hr
Test 2	0, 312.5*, 625*, 1250*, 2500*, 3750, 5000	24 hr	-
Present			
Test 1	0, 39.06, 78.13, 156.25, 312.5*, 625*, 1250*	4 hr	20 hr
Test 2	0, 39.06, 78.13, 156.25, 312.5*, 625*, 1250*	4 hr	20 hr

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>1250	≥156.25	Negative
Test 2	>5000	2500	≥312.5	Negative
Present				
Test 1	>5000	>1250	≥156.25	Negative
Test 2	>5000	>1250	≥312.5	Negative

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

TEST FACILITY SafePharm (2007c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Biodegradability in seawater

TEST SUBSTANCE	Notified 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 notified chemical 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 the notified chemical was in the range 3–6% based on the chemical oxygen demand. The limited degradation of the notified chemical 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 notified chemical 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 notified chemical described above.
CONCLUSION	The notified chemical is not easily biodegradable in seawater.
TEST FACILITY	IUCLID (2006)

C.1.2. Bioaccumulation

Remarks	The water soluble components of the notified chemical are not expected to bioaccumulate based on their low estimated water-oil partitioning coefficients and their ionised form in water at environmental pHs. The

water insoluble components of the notified chemical 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.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE: Soltex Additive

METHOD: OECD TG 203 Fish, Acute Toxicity Test, Modified for Salt Water Species – (Semi-Static)

Species	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 artificial seawater with an initial salinity level of 35 g of NaCl per litre and a pH of 8.1. The tests were carried out at 15°C on turbot that, at the end of the test, had a mean length of 43.5 mm and a mean weight of 2.13 g. The test solutions of the notified chemical were prepared as water accommodated fractions (WAFs). This involved suspension of the solid test substance in the artificial seawater test medium for 20–24 hours with stirring, followed by a period of settling for 4 hours. The settled solution was filtered through a 63 μm filter and the filtrate was used as the test solution. The test and control solutions were replaced after 48 hours of exposure to the fish. The 72- and 96-hour LC50 toxicity end-points and the associated 95% confidence intervals (CIs) were estimated by means of the Trimmed Spearman-Karber method. There were insufficient data for this analysis at the 24- and 48-hour time points.

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality*				
Nominal		*0 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0	0
560	7	0	0	0	0	0
1000	7	0	0	0	0	0
1800	7	0	0	1	4	4

LC50	> 1800 mg/L at 24 hours. > 1800 mg/L at 48 hours. 1672 (95% CI: 1194–2342) mg/L at 72 hours. 1672 (95% CI: 1194–2342) mg/L at 96 hours.
NOEC	1000 mg/L at 96 hours.
Remarks – Results	There were no mortalities in the procedural control vessels and the environmental test parameters remained within the specified limits. The test is therefore valid. After 24 hours, sedimentation of the notified chemical was observed in the test solutions. The quantity of sediment appeared to increase over time and was greater for higher nominal concentrations. These observations indicate that the WAFs were unstable with respect to the

solubility of the notified chemical and that the actual exposure concentration was not constant over the 48-hour exposure period for each batch of test solution. Based on these observations, and the estimated solubility of the notified chemical, it is calculated that the actual concentration of the notified chemical in the WAFs is likely to have been < 40% of the nominal value. The indicated end-points are all based on nominal WAF loading levels.

There were no indications in the test report of any non-lethal toxic effects on fish in any of the test solutions. The indicated NOEC value is therefore based solely on the absence of mortality in fish in the test vessels.

The calculated 96-hour LC50 for the notified chemical based on nominal WAF loading levels is significantly greater than the 100 mg/L threshold figure indicated as harmful to fish under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations 2003). Therefore, the notified chemical is classified as not harmful to fish.

CONCLUSION The notified chemical is not harmful to fish.

TEST FACILITY Chemex Environmental International (2002)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified 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 notified chemical 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 notified chemical 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 10–1000 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 notified chemical 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)*
1000	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.

EC50 > 1000 mg/L at 24 hours
380 (95% CI: 330–440) mg/L at 48 hours

NOEC 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 notified chemical and was most pronounced for the 1000 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 1000 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 notified chemical. 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 notified chemical in the range 18–1000 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 notified chemical 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 for the notified chemical based on nominal concentrations is significantly greater than the 100 mg/L threshold figure indicated as harmful to invertebrates under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations 2003). Therefore, the notified chemical is classified as not harmful to invertebrates.

Additional Related Studies from IUCLID

The conclusions of this study are consistent with three additional studies of the toxicity of the notified chemical 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 notified chemical 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 notified chemical in aged, filtered, and aerated synthetic seawater. The test substance was derived from a drilling fluid containing the notified chemical, 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 notified chemical 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 notified chemical 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 notified chemical 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 notified chemical 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 notified chemical is not lethally toxic to *Macoma nasuta*.

CONCLUSION

The notified chemical is not harmful to invertebrates.

TEST FACILITY Safepharm (2005b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified 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 notified chemical 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	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*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 (95% CI: 1.5–4.3) mg/L) 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 1000 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 notified chemical 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 1000 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 1000 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 notified chemical 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 notified chemical 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 notified chemical is classified as not harmful to algae.

Additional Related Study from IUCLID

The toxicity of the notified chemical 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 notified chemical, 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 notified chemical 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, p. 9). Hence, the results from this earlier algal toxicity test are not considered indicative of the chemo-toxicity of the notified chemical and have not been included in

	the environmental risk assessment.
CONCLUSION	The notified chemical is not harmful to algae.
TEST FACILITY	Safepharm (2005c)

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