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September 2007

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sulfomethylated Tannins

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and *Industrial Chemicals (Notification and Assessment) Regulations 1990*. 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 and Water Resources.

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
Chevron Philips Chemicals Australia Pty Ltd. (ABN 29 107 015 896)
Suite 409, 685 Burke Rd.
Camberwell VIC 3124

NOTIFICATION CATEGORY
Standard: Biopolymer (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Melting point
- Boiling point
- Vapour Pressure
- Water solubility
- Hydrolysis as a Function of pH
- Partition Co-efficient
- Absorption/Desorption
- Dissociation Constant
- Particle size
- Flash Point
- Flammability Limits
- Autoignition Temperature
- Explosive Properties
- Reactivity
- Acute oral toxicity
- Acute dermal toxicity
- Acute inhalation toxicity
- Dermal irritation
- Eye irritation
- Dermal sensitisation
- Repeat dose toxicity
- Induction of point mutations
- Chromosome Damage
- Induction of germ cell damage

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None. An analogue, Sulfited Tannins (CAS No. 72854-27-4), has been notified in Canada.

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Tannins, sulfomethylated

OTHER NAME(S)
Sulfomethylated Quebracho

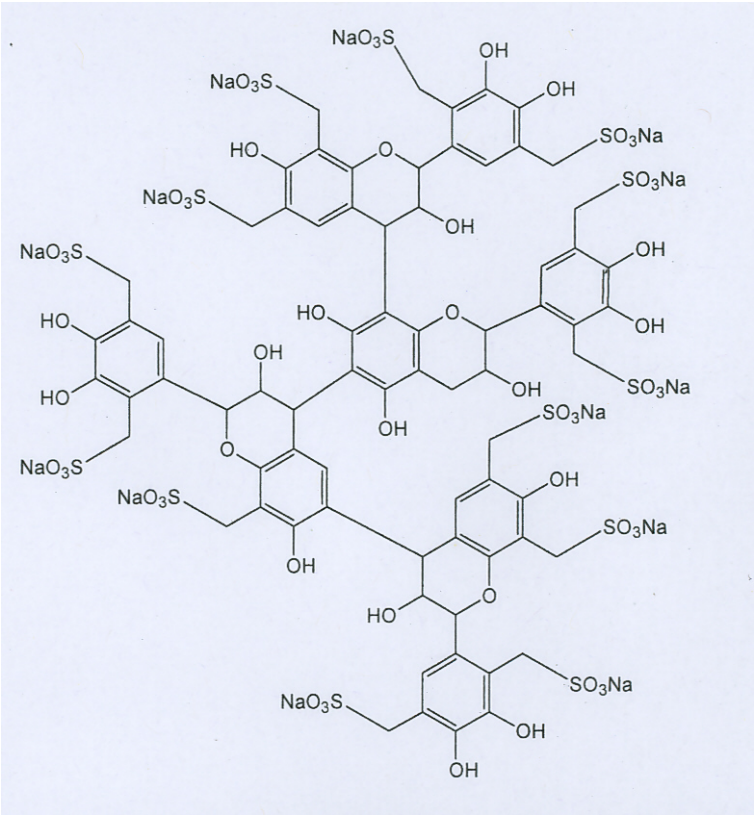
Sulfomethylated tannins
Tannin sulfomethylated

MARKETING NAME(S)
Drill-Thin® Thinner
Chrome-free Desco®
Chrome-free Desco® II
SMQ
Orfom® Grade 3 Tannin

CAS NUMBER
68201-64-9

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



The notified polymer is a sulfomethylated derivative of Quebachro extract (a condensed tannin). It is difficult to analyze and identify every single chemical or polymeric species in this complex biological mixture, however it is believed to be largely composed of dimers, trimers and tetramers. The figure above is a representative structure of a fully sulfomethylated tetramer.

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	2737
Weight Average Molecular Weight (Mw)	23627
Polydispersity Index (Mw/Mn)	8.64

ANALYTICAL DATA
Reference IR, FTIR, and UV/Vis spectra were provided for both the notified biopolymer and the analogue, Sulfited Tannins which indicates close similarities with slight differences consistent with the different methods of sulfonation.

ANALOGUES AND RELATED CHEMICALS

As there was a lack of information on the notified chemical, data on the physical-chemical properties and toxicity of analogues and related chemicals was evaluated as part of this assessment. The identity of these chemicals is described below.

Analogues

Sulfited tannins is considered to be a close analogue for the notified biopolymer. Sulfited tannins is produced by the reaction of tannins extract with sodium bisulfite, sodium polysulfide and sodium sulfide whereas the notified biopolymer is the product of reaction between tannins extract from the Quebracho tree and sodium formaldehyde bisulfite (see more details in section 3 below). The difference between these two substances is that the notified biopolymer contains a methylene group between the reactive sulfonic acid moiety and the tannin molecule. In each case the reaction decreases viscosity and eliminates the tendency of precipitates forming in dilute aqueous solutions.

Quebracho extract is the non-sulfomethylated analogue of the notified biopolymer. Hawthorn extract is a UVCB substance which contains similar tannins (i.e. condensed tannins) to Quebracho extract.

Related chemicals

Tannins are prevalent in the environment and are common constituents in the human diet. Dietary sources of tannins include tea, fruit (such as grapes), wine, and vegetables, such as corn. There are two types of tannins: condensed tannins such as the notified biopolymer (also known as proanthocyanidins or procyanidins); and hydrolysable tannins, such as the gallotannin which is the major constituent of commercial grade tannic acid. While both types are polyphenolic compounds, the hydrolysable tannins differ from the condensed tannins as they are derivatives of gallic acid in which the gallic acid is esterified to a core polyol (e.g. glucose). An IUCLID dataset and USEPA report exists for the chemical 'tannin (tannic acid)' with CAS number 1401-55-4. As it is not clear from these reports whether the tannins tested are hydrolysable tannins or condensed tannins the data is considered to be supporting information, rather than analogue data. Hydrolysable tannins are more likely to be absorbed across biological membranes and therefore may represent a worst case for the toxicity of tannins in general.

3. COMPOSITION

DEGREE OF PURITY

100% pure as manufactured

IMPURITIES/RESIDUAL MONOMERS

The notified biopolymer is derived from Quebracho tannin, an extract of the bark of the Quebracho tree (*Aspidosperma quebracho).* Quebracho tannin is characterised by the presence of condensed oligomers of resorcinol and pyrogallol. The notified biopolymer is a sulphur methylated derivative and is of variable composition. It is not possible to identify impurities which are not commercially functional.

A standard manufacturing method is carried out by treating a known amount of commercially available quebracho with sodium hydroxide in water at about 88°C until the biopolymer dissolves (Solution A). A second solution containing known amount of sodium bisulfite and formalin (36%) is made in a separate container (Solution B). Then, Solution B is added to Solution A and allowed to react for 30 min. The mixture is then maintained at about 71°C for 1.5 h. The resultant solution is dried to recover the notified biopolymer (SMQ). When a salt other than sodium is required, for example iron, a solution of the inorganic salt (e.g., FeSO4) is treated with the SMQ solution at 71°C for 1.5 h and then dried.

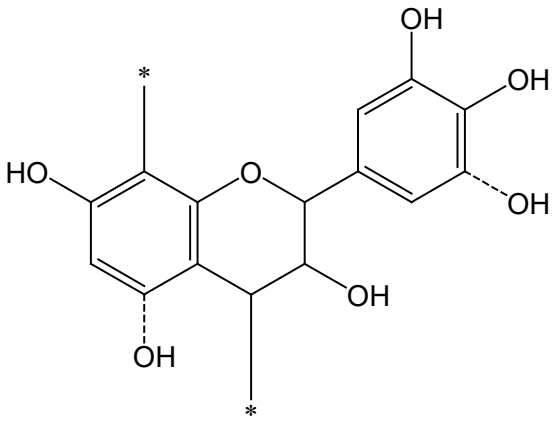
ADDITIVES/ADJUVANTS

None

POLYMER CONSTITUENTS

The notified biopolymer consists of Quebracho extract reacted with sodium bisulfite (sulphurous acid, monosodium salt; CAS No: 7631-90-5) and formaldehyde (CAS No: 50-00-0). Quebracho is characterised mainly by the presence of condensed oligomers of C15 polyphenols. These C15 structures consist of

resorcinol/phloroglucinol and pyrogallol/catechol linked by a central heterocyclic pyran ring (ITEQ, 1970) as follows:



4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Fine reddish brown powder with mild tree bark odour

Property	Value	Data Source/Justification
Melting Point/Freezing Point	≥ 200ºC	Estimated based on value for tannin
Boiling Point	Not applicable	Decomposed at melting point
Density	1380 kg/m^3 at 28ºC	Measured
Vapour Pressure	≤ 1.18 × 10^{-29} kPa	Estimated based on EPIWIN value for tannin
Water Solubility	≥1000 g/L at 20ºC	Analogue data (sulfited tannins)
Hydrolysis as a Function of pH	Not determined	The notified biopolymer does not contain any functional groups susceptible to hydrolysis.
Partition Coefficient (n-octanol/water)	log P_{ow} = -3.28 to -3.19	Measured
Adsorption/Desorption	log K_{oc} -2.42 to -2.35	Estimated
Dissociation Constant	pKa = < 0†; 6.96*	†Sulphonic acid group; *Analogue data for phenolic group.
Particle Size	Not determined.	
Flash Point	≥ 199ºC	Estimated based on value for tannin
Flammability	Non-flammable	Estimated based on value for tannin
Autoignition Temperature	≥ 526ºC	Estimated based on value for tannin
Explosive Properties	Not explosive	Estimated based on the chemical structure

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

Not expected to be reactive based on structure.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED BIOPOLYMER (100%) OVER NEXT 5 YEARS

The notified biopolymer is not manufactured in Australia. It is imported as raw a material (100%) in powder form for use in drilling mud.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100	100	100	100	100

PORT OF ENTRY
Darwin, Dampier, Adelaide, Fremantle, Melbourne and Brisbane.

IDENTITY OF MANUFACTURER/RECIPIENTS
Approximately 30 oil and gas wells will receive the notified biopolymer in the next five years.

TRANSPORTATION AND PACKAGING
The imported notified biopolymer in polyethylene-lined paper bags (11.3 to 22.6 kg) is transferred from the port of entry to drilling sites on shrink-wrapped pallets by trucks and stored on site prior to use.

USE
The notified biopolymer will be used in oil and gas well drilling operations (both on-shore and off-shore). It is used as viscosity modifier for thinning the drilling mud during drilling operation.

OPERATION DESCRIPTION
On-shore operation
At the drilling site, the pallets are opened and the bags containing the notified biopolymer are used one at a time. They are cut and manually added to a hopper. The hopper is connected to a pipe through which the drilling mud is transferred to the drill shaft. The mud is travelling at high speed and draws the notified biopolymer via a venturi effect. The concentration of the notified biopolymer in the mud is approximately 0.5%. Normally about 1000 barrels of mud containing the notified biopolymer are used throughout the drilling operation. A single drilling operation may use about 3000 kg of the notified biopolymer per year.

Off-shore operation
Similar procedures are followed at the off-shore site. The mud and the drill cutting containing the notified biopolymer is pushed out of the well and transferred to the surface for solids processing.

Processing involves a sifting as well as sedimentation of solids in a low speed centrifuge in order to remove the drill cuttings. Drilling mud containing the notified biopolymer is then supplemented with additional mud for additional drilling.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and storage	30	8 h/shift	< 230 d/year
Drilling worker	30	1 h/shift	< 230 d/year

Exposure Details
Transport and storage workers should only be exposed to the notified biopolymer in the event of accidental rupture of the bags.

Dermal, ocular and inhalation exposure may occur during manual addition of the imported powder to the hopper. Ventilation will be site dependent. Most operations are carried out in the open air, while under inclement weather conditions in some regions the operation is conducted in suitable enclosures with proper ventilation. Usually, the area around the hopper is under an adequate shelter that is open in all sides to keep the workers and the equipment out of the elements. With routine use of personal protective equipment, the workers' exposure via all routes is expected to be minimised.

Once the notified biopolymer is in the drilling mud at 0.5%, exposure of workers should not occur.

6.1.2. Public exposure

The notified biopolymer is for industrial use only, so it is not available for the general public. The extent of public exposure is considered negligible.

6.2. Human health effects assessment

There is no toxicity data available on the notified biopolymer itself. The results from toxicological investigations conducted on analogues of the notified biopolymer are summarised in the table below. Details of these studies can be found in Appendix B. In addition there is toxicological data available on related biopolymers, such as tannic acid, and other tannins or plant extracts containing tannins. These biopolymers may be hydrolysable tannins and therefore not direct analogues for the notified biopolymer, however the toxicity data is considered to be supporting information for the evaluation of the toxicity of the notified biopolymer. This information is summarised in Appendix B and discussed in the text below.

Endpoint	*Test Substance*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	Hawthorn extract (hydroalcoholic solution containing 18.75% oligomeric procyanidins)	LD50 > 3000 mg/kg bw, low toxicity
Rat, acute inhalation toxicity	Sulfited tannins	LC50 > 6.66 mg/L/4 hour, low toxicity
Rat, dog repeat dose oral toxicity – 26 weeks.	Hawthorn extract (hydroalcoholic solution containing 18.75% oligomeric procyanidins)	NOEL = 300 mg/kg bw
Sheep, repeat dose oral toxicity – 21 days	Quebracho extract	NOEL = 1500 mg/kg live weight /day
Genotoxicity – bacterial reverse mutation	Sulfited tannins	non mutagenic

Acute toxicity

The notified biopolymer is likely to be of low toxicity via the oral route based on the acute oral toxicity of the non-sulfomethylated analogue substance Hawthorn extract. In addition the acute oral toxicity of a number of non-sulfomethylated tannins has been investigated and found to have low toxicity via the oral route. It should also be noted that tannins, and condensed tannins in particular, are found in a number of food items regularly consumed by humans, including lentils (up to 1040 mg/100g), fruit (up to 160 mg/ 100g in grapes), and wine (Santos-Buelga and Scalbert, 2000). It is also likely to be of low toxicity via the inhalation route in rats based on a study using the close analogue sulfited tannins.

Irritation and sensitisation

No information regarding irritation or sensitisation was available on the direct analogues of the notified biopolymer. However, based on the irritancy and sensitising potential of related chemicals such as tannic acid and procyanidin B-2 (a condensed tannin), as well as that of the component monomers, the notified biopolymer is expected to be at most slightly irritating to skin and eyes, and not sensitising to skin. The notified biopolymer does not contain any structural alerts for sensitisation.

Repeated dose toxicity

The notified biopolymer is likely to be of low chronic toxicity on the basis of oral repeat dose studies in rats and dogs with Hawthorn extract and in sheep with Quebracho extract (both non-sulfomethylated analogues). It is worth noting that plant extracts from Hawthorn, Grape seed and pine bark (for example), which contain a range of non-sulfomethylated analogues of the notified biopolymer are readily available to consumers, marketed as antioxidants and are presumed to be consumed as herbal remedies on a long term basis. There appear to be no reports of significant adverse side effects.

Mutagenicity
The notified biopolymer is not likely to be a mutagen based on the results from a bacterial reverse mutation study conducted on the analogue sulfited tannins. In addition the related biopolymer tannic acid was found to be non-genotoxic in an in vivo test on germ cells in *D. melanogaster.*

Additional studies on related chemicals
In developmental toxicity studies the related biopolymers tannic acid and Peruvian Tara tannin were found to be not developmentally toxic in rats or mice. In carcinogenicity studies the related biopolymers tannic acid and Bracken Fern tannin were found to be not carcinogenic in rats.

Based on the available data the notified biopolymer is not 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

Although no toxicity studies have been carried out on the notified biopolymer, it belongs to a class of compounds, the tannins, which have been studied for various reasons. The analogues and related chemicals tested were not acutely or chronically toxic, were unlikely to be irritating to skin and eyes or sensitising to skin, were unlikely to be developmentally toxic or genotoxic and were not likely to be carcinogenic. The close analogue sulfited tannins was specifically tested for inhalation toxicity and was of low toxicity. Although the notified biopolymer is a dust, the particle size is unknown. Therefore, it should be assumed to be respirable and exposure in the workplace should be kept below the ACGIH recommended TLV of 3 mg/m^3. On the drilling sites, the hopper into which bags of the notified biopolymer are manually tipped is usually in the open air. However, as the transfers are manual some dust cloud generation can be expected and this necessitates the use of a dust mask or respirator.

Workers other than those on drilling sites (i.e. transport and storage workers and drilling workers not specifically charged with transfer of the notified biopolymer to a hopper for addition to drilling mud) should not be exposed to the notified biopolymer. Once it has been transferred to drilling mud at 0.5% worker exposure is unlikely.

6.3.2. Public health

The public are unlikely to be exposed to the notified biopolymer except in the event of a transport accident involving rupture of import bags. Therefore adverse public health effects are unlikely.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The polymer is not manufactured or reformulated in Australia. Therefore no release is expected, except in the unlikely event of a spill where the packaging is breached.

RELEASE OF CHEMICAL FROM USE
The chemical is expected to be used in drilling muds for on-shore and off-shore drilling operations. The chemical is a powder and minimal amounts (0.1%; < 100 kg per annum) are expected to remain in the "empty" bags. The residue will be disposed of to landfill. The remainder of the chemical (< 100 tonnes per annum) is expected to be used in its intended manner. It is expected that each well will use approximately 3000 kg (and a maximum of 3330 kg) per annum at a maximum of 30 wells. The notified biopolymer is added to drilling muds at a rate of 3 pounds (1.4 kg) to every 600-700 (272-318 kg) pounds of mud, equivalent to 0.5% (w/w).

During drilling operations, the mud (comprised largely of bentonite clay) is pumped down the drill

shaft and 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 deep well drilling. The drilling mud is pushed out of the well and transferred to the surface for solids processing. This involves a sifting along with low speed centrifugation in order to remove the drill cuttings. The drilling mud containing the notified polymer is recovered and then replenished with additional mud containing more notified polymer and is transferred back down into the well. The drill cuttings that represent about five to ten percent of the material transferred to the surface contain some entrained drilling mud containing the notified biopolymer. The entrainment of trapped chemical after separation is expected to be at most 15% but with more modern techniques this is likely to be closer to 5%. (International Association of 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 are discharged into the ocean.

RELEASE OF CHEMICAL FROM DISPOSAL

The precise extent to which the notified biopolymer is expected to remain adhered to the drill cuttings or drilling mud is not fully understood. However, there is evidence that it will mostly remain adhered to the surface of the drilling mud clay, with some being released to the ocean environment. The residue in empty bags is expected to be disposed of to landfill.

7.1.2 Environmental fate

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

7.1.3 Predicted Environmental Concentration (PEC)

The notified biopolymer is water soluble and has a low K_{oc}, indicating that it will be released from the drilling mud to the seawater. However, plant tannins and their derivatives (including the notified biopolymer) used as drilling mud thinners are negatively charged and are expected to adhere to the surface of the bentonite clay entrained in the drill cuttings (Darley, 1988). No test reports are available and a worst case scenario is considered for the aqueous environment where the entire chemical is released and a worst case for the benthic zone is considered where none is released from the clay.

A worst case scenario for the aquatic environment may be calculated as follows based on the following assumptions:

- A daily and continuous discharge of the notified biopolymer.
- Complete release of the chemical from the drilling cuttings containing entrained drilling mud.
- Release into an area having a cone shape model (based on the predicted movement of the discharge).
- A fixed discharge diameter (r_1 = ~0 m^2) (release point of notified biopolymer) into the ocean.
- A fixed depth value (h = 100 m) (height from the drilling platform to the ocean floor).
- Consideration of the ocean floor diameter (r_2 up to 500 m). (This value is the distance considered by the CHARM model for its evaluation of environmental risk)
- Current flows are not taken under consideration.
- Steady dissipation rate.
- Degradation rates based on ready biodegradability in seawater results.

A maximum of 3000 kg per annum is used at any one offshore well and all wells are assumed to be sufficiently remote from each other as to not contribute to each others PEC.

Using this model it is expected that a steady state amount of chemical will be reached when the rate of degradation (K_1) is equal to the rate of discharge (K_2). That is amount of notified biopolymer = $K_2 \div K_1$. K_1 was calculated from a regression of degradation versus time and a value of 0.01796 day^{-1} was derived with an approximate half life of 39 days. K_2 is equal to 9.12 kg/day (3330 kg per annum ÷ 365 working days.) The steady state amount is therefore 508 kg.

Concentration of notified biopolymer at various distances from the discharge point

Distance from discharge (m)	Volume of water (kL)	Concentration (µg/L)
10	10472	48510
25	65450	7762
50	261799	1940
100	1047198	485
200	4188790	121
300	9424778	54
400	16755161	30
500	26179939	19

For the benthic environment a worst case scenario may be considered for the concentration of the notified biopolymer in the drill cuttings. Assuming 100% retention of the notified biopolymer in the drilling mud and 15% entrainment of the mud in the cuttings a value of 750 ppm is derived (0.5% notified biopolymer in the drilling mud × 15% entrainment of the drilling mud in the processed drilled cuttings being disposed of overboard). This scenario may occur in drill cutting piles, but benthic organisms are not expected to live in freshly deposited piles.

However, a more realistic scenario allowing for dispersal of the chemical over 500 m (consistent with the CHARM model) from the discharge point could be calculated as follows. Again it is assumed that a steady state amount of 508 kg of notified biopolymer is reached and that all of this is adsorbed to the sediment. The total volume of sediment affected is $\pi r^2 d$. If the depth (d) is taken to be 5 cm (the aerobic zone), the resulting amount of sediment is 39 270 m^3. If the density is approximately 1.2 g/cm^3 (default value) then this results in 47 100 tonnes. The resulting PEC for the benthic system is 10.8 mg/kg of sediment.

In the case of on-shore drilling, these are discharged into lined reserve pits for later treatment. The reserve pits for on-shore drilling operations 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.

The notified biopolymer is expected to slowly breakdown in seawater to sodium ions, sulphates, oxides of carbon and water.

7.2. Environmental effects assessment

Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 ≥ 1800 mg/L	Practically non toxic, but treat with caution as the actual concentration of the notified biopolymer in the test solutions may have been much lower than the nominal amount.
Copepod Toxicity	EC50 73.2 mg/L	Harmful
Algal Toxicity	ErC50 2.15 mg/L	Toxic
Lemna Toxcity	EC50 ≥ 1000 mg/L	Practically non toxic
Amphipods	EC50 ≥ 12 821 mg/kg	Practically non toxic

7.2.1 Predicted No-Effect Concentration

The PNEC for the aquatic environment is calculated from the lowest ErC50 for algae for 72 hours, which was 2.15 mg/L and dividing by 100 as toxicity data is available for three trophic levels. A value of 21.5 µg/L is derived.

The PNEC for the benthic compartment is calculated from the LC50 for the single semi-chronic test for *Corophium* and applying an assessment factor of 100. The safety factor of 100 is applied as there is a semi chronic test and tests for three trophic levels for the aquatic environment. However, the interaction between the benthic and aquatic environment is complex and cannot be considered in the same manner as trophic levels. A value of 128 mg/kg is derived.

7.3. Environmental risk assessment

Risk Quotient Table 1 (PEC/PNEC)
Worst Case

Risk Assessment	PEC µg/L or mg/kg	PNEC µg/L or mg/kg	Q
Q - Ocean:			
10	43736	215	2256
25	6998	215	361
50	1749	215	90.3
100	437	215	22.6
200	109	215	5.64
300	49	215	2.51
400	27	215	1.41
500	17	215	0.90
Q – Benthos worst case	750	128	5.86

The notified biopolymer shows a potential risk to the marine environment for distances up to 400 m from the discharge point. However, the risk quotient falls below 1 before the distance of 500 m, which is the distance assessed in the CHARM model. Although there may be adverse effects, being consistent with the CHARM model these may be considered localised.

Further the model does not allow for refreshing of the seawater and some of the notified biopolymer is expected to remain bound to drilling mud. A worst case refreshment rate according to the CHARM model is 0.24 day^{-1}. This is expected to greatly reduce the risk to the marine environment. If the model is refined using a worst case refreshment rate of 0.24 day^{-1} then the steady state amount in a region of interest may be calculated in a similar manner as the steady state amount due to degradation. As the refreshment rate is much greater than the degradation rate (K_1) then the steady state amount may be calculated from when the rate of refreshment (K_3) is equal to the rate of discharge (K_2). That is amount of notified biopolymer = $K_2 \div K_3$ (9.12 kg/day ÷ 0.24 day^{-1}). A value of 38 kg is derived. If it is further assumed that 50% of the notified biopolymer adheres to the bentonite clay present in the drill cuttings then a value of 19 kg is calculated.

Risk Quotient Table 2 (PEC/PNEC)
Mitigated - allowing for adherence to bentonite clay and removal of notified biopolymer by refreshment for the marine environment; and degradation for the benthic zone.

Risk Assessment	PEC µg/L or mg/kg	PNEC µg/L or mg/kg	Q
Q - Ocean:			
10	1814	215	84.39
25	290	215	13.50
50	73	215	3.38
100	18	215	0.84
200	5	215	0.21
300	2	215	0.09
400	1	215	0.05
500	1	215	0.03
Q – Benthos more realistic scenario	10.8	128	0.08

The refined model shows potential risk to the marine environment for distances up to ~ 100 m from the discharge point. Again in accordance with the CHARM model this can be regarded as localised.

For benthic dwelling organisms a potential risk is shown for freshly deposited drill cuttings. (Table 1) However, it is unlikely that such organisms will live in freshly deposited piles of cuttings. A more realistic scenario shows an acceptable risk to the benthic environment (Table 2).

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

Based on the available data the notified biopolymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances*.

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

	Hazard category	***Hazard statement***
Environment	2	Toxic to aquatic life

8.2. Human health risk assessment

8.2.1. Occupational health and safety

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

8.2.2. Public health

When used in the proposed manner the risk to the public is considered to be acceptable.

8.3. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The notified biopolymer is not considered to pose a risk to the environment other than in a localised area (< 100 m) in the vicinity of off-shore based drilling platforms.

9. MATERIAL SAFETY DATA SHEET

The MSDS of the notified biopolymer provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS was found to be in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003).

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified biopolymer as introduced:
  - Generation of dust clouds should be minimised when the notified biopolymer is transferred to the hopper of drilling equipment.

- Employers should ensure that the following personal protective equipment is used by

workers to minimise occupational exposure to the notified biopolymer as introduced:
- Dust mask or respirator.

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 biopolymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified biopolymer should be disposed of by authorised landfill.

Emergency procedures

- Spills or accidental release of the notified biopolymer should be handled by physical collection, such as sweeping while avoiding creating dust. Collect for re-use to the extent practicable or place in suitable containers for disposal.

11. REGULATORY OBLIGATIONS

This risk assessment is based on the information available at the time of notification. If the circumstances under which the notified biopolymer was assessed change a reassessment may be needed. Under the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified biopolymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified biopolymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of Chemicals Notification and Assessment 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 notified biopolymer has changed from drilling mud additive or is likely to change significantly;
- the amount of notified biopolymer being introduced has increased from 100 tonnes per annum, or is likely to increase, significantly;
- if the notified biopolymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified biopolymer 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.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Melting Point/Freezing Point ≥ 200°C (estimated)

Remarks Estimated from the melting point (decomposes at 200°C) of the related chemical tannin (Sax, 1984).

Boiling Point Not applicable

Remarks The related chemical tannin decomposes at the melting point (200°C).

Density 1380 kg/m^3 at 28°C

METHOD API Method 13A Section 7.2 (ISO 3500) 1998.

Remarks A Le Chatelier flask was filled with kerosene to a predetermined mark and equilibrated in a constant temperature water bath. Pre-dried notified biopolymer is added and dissolved. The density was calculated from the weight of biopolymer added and the difference in volumes of the flask contents.

TEST FACILITY In house test by notifier.

Vapour Pressure ≤1.18×10^{-29} kPa (estimated)

Remarks Estimated for the related chemical Tannins by EPIWIN version 3.12.

Water Solubility ≥ 1000 g/L at 20°C

METHOD OECD TG 105 Water Solubility.

Remarks Flask Method. A preliminary test was conducted in water, and buffers of pH 5, 7 and 9. The sulfited tannin analogue was observed to be soluble at concentrations up to 1000 mg/L. The notified biopolymer is expected to have slightly lower water solubility than the analogue.

TEST FACILITY Inveresk (1997)

Hydrolysis as a Function of pH Not determined.

Remarks The notified biopolymer does not contain any functional groups susceptible to hydrolysis.

Partition Coefficient (n-octanol/water) log P_{ow} = -1 at 20°C

METHOD OECD TG 107 Partition Coefficient (n-octanol/water)

Remarks The sulfited tannin analogue was tested by the Flask Method. The aqueous phase was a buffer of pH value 7.

TEST FACILITY Inveresk (1997)

Partition Coefficient (n-octanol/water) log P_{ow} = -3.28 to -3.19

METHOD SOP ENV 214 based on OECD Guidelines for Testing of Chemicals 117 Partition Coefficient (n-octanol/water).

Remarks The Pow of the test substance was determined using the HPLC method. These values were considerably below the lowest reference substance (2.1 for benzene) and may not be reliable. However, it can be confidently stated that the results are considerably below the value of 3.0

TEST FACILITY Chemex (1998a)

Adsorption/Desorption – screening test Not measured

log K_{oc} = -2.42 to -2.35 for notified biopolymer; -0.535 for the sulfited analogue.

METHOD

Remarks Estimated from log Pow value.(log Koc = 0.827 × log Kow + 0.292). Although the

notified biopolymer is expected to have little affinity for organic carbon the negatively charged sites are expected to bind to cations in clay and sediments.

Dissociation Constant pKa = 6.96

METHOD OECD TG 112 Dissociation Constants in Water.
Remarks Dissociation constant for the analogue sulfited tannins measured via titration with 10 mM NaOH.
TEST FACILITY Inveresk (1997).

Particle Size Not determined.

Remarks The particle size for the analogue sulfited tannins was determined for a ground powder used for the inhalation toxicity study (MMAD = 8.3 μm) but the particle size of unground material was not measured.

Flash Point ≥ 199°C

Remarks Estimated from the flash point for the related chemical tannins (Sax, 1984)

Flammability Non-flammable.

Remarks Information provided in the IUCLID dataset for the related chemical Tannins (European Commission, 2000)

Autoignition Temperature ≥ 526°C

Remarks Estimated from the autoignition temperature for the related chemical tannins (Hawley, 1997)

Explosive Properties Not explosive.

Remarks Estimated based on the chemical structure and on the explosive properties for the related chemical tannins (European Commission, 2000)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

No data were available for the notified biopolymer. However, data were available for analogues (sulfited tannins, Hawthorn extract, Quebracho extract) and related chemicals (tannins, tannic acid). Some toxicity studies have been conducted on the related chemical procyanidin B2 on the basis of a proposed use as a hair restorative (Takahashi, 1999).

B.1. Acute toxicity – oral

Studies on Hawthorn extract containing various polyphenolic procyanidins (WHO, 2002) have shown that rats and mice tolerate 3000 mg/kg bw, by gastric lavage, of a standardised hydroalcoholic extract of the leaves with flowers (containing 18.75% oligomeric procyanidins) without any clinical symptoms of toxicity.

The acute oral LD_{50} for Tannin (CAS No. 1401-55-4) was reported as > 3000 mg/kg bw in rats (species unspecified). Acute oral LD_{50} values in rats for various tannins were established as 1550 mg/kg bw (Aleppo), 3700 mg/kg bw (Tara), 2800 mg/kg bw (Chinese), 2650 mg/kg bw (Sicilian sumac) and 7500 mg/kg bw (Douglas fir) (USEPA, 2006).

The lethal dose of procyanidin B2 was reported as greater than 2000 mg/kg (subcutaneous injection) (Takahashi, 1999).

B.2. Acute toxicity – dermal

Data not provided.

B.3. Acute toxicity – inhalation

TEST SUBSTANCE	Orform Grade 2 Tannin (solubilised sulphited Quebracho extract)
METHOD	OECD TG 403 Acute Inhalation Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley
Method of Exposure	Whole-body exposure.
Exposure Period	4 hours
Physical Form	Solid aerosol (particulate).
Particle Size	MMAD = 8.264 μm
Remarks - Method	No deviations from protocol noted.

RESULTS

Group	*Number and Sex of Animals*	*Concentration mg/L*		*Mortality*
		Nominal	*Actual*	
1	5/sex	92.7	6.66	1 male

LC50	> 6.66 mg/L/4 hours
Signs of Toxicity	Two males and three females lost weight between days 0 and 7. Clinical signs included activity decrease, corneal opacity, crust around the eyes and nose, gasping, nasal discharge, piloerection, polyuria, ptosis, respiratory chirp, salivation and withdrawn testes. Surviving animals were asymptomatic by day 5.
Effects in Organs	Abnormal necropsy findings occurred only in the animal that died on test and were red fluid in the nostrils, lungs dark red, slightly swollen and uninflatable and fluids in the trachea and bronchi.
Remarks - Results	None.
CONCLUSION	The notified biopolymer is of low toxicity via inhalation.
TEST FACILITY	Stillmeadow (1996)

B.4. Irritation and sensitisation

For irritant properties some eye irritant effects of tannic acid have been noted in rabbits although it is reported that studies on the use of tannic acid for emergency treatment of eyes contaminated with dyes have revealed no deleterious effects (Grant, 1974). The notified biopolymer would be predicted to be a skin and eye irritant on the basis of the hazard classification of one of the components of its constituent monomer resorcinol (HSIS, 2007) although it should be noted that pyrogallol, the other component of the monomer is not classified as an irritant.

Primary irritation tests using rabbits indicated that procyanidin B2 containing preparation shows no primary irritation. In the guinea pig maximization test, there was no evidence of sensitisation to procyanidin B2. In primary ocular irritation tests using rabbits, procyanidin B2 containing preparation and vehicle showed slight irritation of conjunctivae which is assumed to be caused by ethanol.

B.5. Repeat dose toxicity

A repeat dose study with Quebracho Tannin Extract was performed in Sheep to validate its use as a feed additive for improving the digestive utilisation of protein-rich feeds (Hervás *et al.*, 2003). Four groups of 4 sheep were dosed intraruminally once daily for up to 21 days with 0, 500, 1500 or 3000 mg Quebracho tannin extract/kg live weight.

In all but the high dose group feed intake was similar. For the high dose group feed intake was essentially nil after 6 days of treatment associated with a loss of 4.7 kg liver weight in 10 days. All sheep in the control low and mid dose groups remained healthy throughout the experiment. Ewes from the high dose group became weak and depressed on day 5 and after 8 days of dosing remained incumbent. At 10 days they were humanely killed. No macroscopic or microscopic changes were noted in the organs of the control, low or mid dose groups. For the high dose group lesions were observed in the digestive tract comprising well-demarcated ulcers filled with necrotic material in the mucosa of the rumen and reticulum associated with distension of the abomasum and small intestine and dense mucous material in the caecum. Some minor renal damage in the high dose group was indicated by an increase in urea nitrogen on day 9 as well as an increase in creatinine. Some oxidative stress in the high dose group was indicated by significant depletion of P-450 and GSH but may have been due partly to anorexia.

No toxic effects were observed in a repeat dose oral toxicity study in which rats and dogs were given a standardised Hawthorn extract (containing 18.75% oligomeric procyanidins) at doses of 30, 90 and 300 mg/kg bw daily by the intragastric route for 26 weeks (WHO, 2002).

According to a report by the USEPA (2006) no effects of tannins (Aleppo, Tara, Chinese, Sicilian sumac or Douglas fir) on subchronic toxicity in rats were observed at dose levels up to 800 mg/kg bw/day. Parameters measured were body weight, food intake and utilisation, liver and kidney weights, macroscopic or microscopic effects in organs.

No adverse effects in rats or dogs were observed at dietary levels of Peruvian Tara tannin equivalent to 125 mg/kg bw/day for 2 years (USEPA, 2006). Parameters measured were food consumption, haematology, organ weights, macroscopic or microscopic effects in organs for both species as well as behaviour in the dogs and survival and growth in the rats.

B.6. Genotoxicity

TEST SUBSTANCE	Orform Grade 2 Tannin
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA98, TA100, TA102, TA97a
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction.
Concentration Range in Main Test	a) With metabolic activation: 20, 200, 2000, 10,000 and 20000 µg/plate b) Without metabolic activation: 20, 200, 2000, 10,000 and 20000 µg/plate

Vehicle	0.9% saline
Remarks - Method	No deviations from protocol noted.

RESULTS

Remarks - Results	No significant increase in mutation frequency was observed above background. No indication of test article precipitation or cytotoxicity was described. Negative controls were as expected and positive controls indicated the sensitivity of the test.
CONCLUSION	The notified biopolymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Nelson Laboratories (1998).

Tannic acid has been shown not to be mutagenic in *S. typhimurium* strains TA 98, TA 100 and TA 1535 with or without metabolic activation for S9 fraction derived from rat or woodchuck liver (USEPA, 2006). Tannic acid from tea was found not to be mutagenic in *S. typhimurium* strains TA 98, TA 100 and TA 1535 with or without metabolic activation.

Mutagenicity tests using bacteria showed procyanidin B2 to be non-mutagenic. Chromosomal aberration tests using CHL cells indicated that procyanidin B2 caused polyploidy but no structural aberrations (Takahashi, 1999).

B.7. Genotoxicity – in vivo

Tannic acid was found not to be clastogenic to germ cells of male *Drosophila melanogaster* (USEPA, 2006). In micronucleus tests for mutagenicity using mice, procyanidin B2 was negative (Takahashi, 1999).

B.8. Developmental toxicity (USEPA, 2006)

Pregnant female mice dosed with tannic acid by oral intubation up to 135 mg/kg bw on days 6 – 15 of gestation exhibited no clear effects on nidation or on maternal or foetal survival. Also no effect on frequency of skeletal or soft tissue abnormalities was observed. Similar results were observed with pregnant female rats dosed at up to 180 mg/kg bw.

A three-generation reproduction study was conducted on male and female rats fed Peruvian Tara tannin at doses in the diet equivalent to 0, 29, 60 or 117 mg/kg bw/day. No effects were observed on fertility, gestation, viability or lactation. Pups at 117 mg/kg bw/day had significantly lower weights at weaning and the NOAEL was established as 60 mg/kg bw/day.

B.9. Carcinogenicity (USEPA, 2006)

Tannic acid given to F344 rats ad libitum at 0.25 or 0.5% in distilled water for up to two years did not significantly increase the incidence of any tumour. It was concluded that tannic acid has no carcinogenic potential in F344 rats or modifying effects on the development of spontaneous tumours.

Tannin isolated from bracken fern was determined to be noncarcinogenic in a 72 week study of rats fed a basic diet containing 0.1% tannin in weeks 0-3, 0.2% tannin in weeks 3-22 and 0.4% tannin in weeks 22-72.

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

ENVIRONMENTAL FATE

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified biopolymer (Sulfomethylated Quebracho)
METHOD	OECD TG 306 A Ready Biodegradability in Sea Water; Closed Bottle Test.
Inoculum	Micro-organisms in sea water from Huttoft (East Coast of UK).
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	Chemical Oxygen Demand (COD)
Remarks - Method	The notified biopolymer is a complex mixture of poly-phenolic substances; therefore a single molecular weight cannot be ascribed to the compound. Accordingly the percentage degradation was calculated as a percentage of COD (for the fully digested chemical) rather than theoretical oxygen demand (ThOD). Duplicate samples of test material (3.5 mg/L) were subjected to coarsely filtered sea water containing micro-organisms. Duplicate references (sodium benzoate) and a toxicity control containing the test substance and the reference substance were also run. A single control was run. Oxygen depletion was measured on a regular basis and compared to the COD and ThOD of the test substance and reference substance respectively.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
3	7	3	48
7	10	7	55
11	15	11	66
14	33	14	66
28	38	28	67

Remarks - Results	The COD was determined to be 0.84 mg O_2/mg of test substance. In the same test the COD of sodium benzoate was determined to be 1.54, which was 92% of the ThOD. The toxicity control showed 49% degradation after 28 days, demonstrating that the test substance was not toxic to the inoculum. The reference substance satisfactorily met the criteria for suitability of test method and culture conditions.
CONCLUSION	The notified biopolymer is not readily biodegradable by micro-organisms in sea water.
TEST FACILITY	Safepharm (2005)

C.1.2. Bioaccumulation

TEST SUBSTANCE	Not tested. The notified biopolymer is water soluble and the log Kow can confidently be stated as below 3.0. It is therefore unlikely to bioaccumulate (Chemex, 1998a).

ECOTOXICOLOGICAL INVESTIGATIONS

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Drill Thin®. The notifier identifies this as the marketing name for the notified biopolymer with no additives or adjuvants. However, the test substance shows markedly different water solubility behaviour (see below) than other tests on SMQ, bringing into question the purity of the test substance.
METHOD	SOP E212 based upon OECD TG 203 Fish, Acute Toxicity Test – semi-static.
Species	Turbot (*Scophthalmus maximus*)
Exposure Period	96 hours
Auxiliary Solvent	None.
Water Hardness	Not specified.
Analytical Monitoring	Visual Observation
Remarks – Method	A preliminary study was performed by preparing a nominal 1000 mg/L solution in standardised artificial seawater. This was mixed for 20-24 hours and allowed to separate for 4 hours. A cloudy black solution with neutrally buoyant material was observed. A water accommodated fraction (WAF) prepared by filtering (63 µm) was used for the test. An unspecified number of fish were exposed to the filtrate. On the results of the preliminary test nominal solutions of the test substance were prepared (as above). An unspecified number of fish (but at least 7 to fulfil OECD TG) were exposed each test concentration. The solutions were renewed every 48 hours. Light: 16 hours light; 8 hours dark Temperature: 14-15°C pH: 7.3-8.4 Dissolved Oxygen: 83-100%. Salinity 31-32 g NaCl/L

RESULTS

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

ND: Not Determined.

LC50	≥ 1800 mg/L at 96 hours.
NOEC	1800 mg/L at 96 hours.
Remarks – Results	Significant amounts of test material remained after the nominal settling period. After filtration (63 µm) further material was observed to precipitate. It is noted that the notified biopolymer is freely soluble in deionised water. It is therefore expected that entire amount of notified biopolymer would be available for dissolution. The precipitation may be due to significant amounts of impurities or possibly formulation constituents, and therefore the actual amount of notified biopolymer may be significantly less than the nominal concentrations. However, precipitation was observed after filtration suggesting that the precipitation may be caused by cations (such as calcium and magnesium) or suspended solids present in the synthetic sea water. No adverse effects were recorded.
CONCLUSION	The test substance is practically non-toxic to turbot. However, this result should be treated with caution as the actual concentration of the notified

biopolymer in the test solutions may have been much lower than the nominal amount.

TEST FACILITY Chemex (2002)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified biopolymer

METHOD Static test conditions according to ISO TC147/SC5/WG2 protocol by Thompson (1990): Water Quality: Determination of acute lethal toxicity to marine copepods (*Copepoda crustacea*)

Species	*Arcatia Tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not reported (synthetic sea water)
Analytical Monitoring	Visual
Remarks - Method	A nominal 1000 mg/L stock solution was prepared by adding test substance to filtered (5 µm) natural sea water from Guernsey Sea Farms and shaking vigorously. The stock solution was allowed to stand for 1 hour. A dark reddish solution was obtained. A preliminary study was performed but no details are recorded. From the results of the preliminary study 4 replicates of 5 copepods were exposed to nominal concentrations of the test substance prepared by dilution of the stock solution. A blank and reference substance (1.0 mg/L 3,5 Dichlorophenol) were also run. Light: 16 Hours light 8 hours dark pH: 7.8-8.3 Dissolved Oxygen: 98-103% Temperature: 19.8°C Salinity: 33-35‰

RESULTS

Concentration mg/L		*Number of Arcatia Tonsa*	*Mortalities*	
Nominal	*Actual*		*24 hours*	*48 hours*
0	Control	20	0	1
25	ND	20	1	2
50	ND	20	0	4
100	ND	20	2	6
200	ND	20	20	20
398	ND	20	20	20

ND: Not Determined

LC50	73.2 mg/L at 48 hours *95%;* CI 59.9-89.5
NOEC	50 mg/L at 48 hours was the highest no observed effect concentration. The test reports that 20-80% mortality for the positive control represents an acceptable level of sensitivity. Accordingly ≥ 20% (≥ 4) mortality could be regarded as a statistically significant result.
Remarks - Results	The solutions were dark reddish in appearance, with no other observations recorded. A single copepod died in the control. The mortality rate of *Arcatia Tonsa* in the reference substance at 48 hours was 65%.

CONCLUSION The test substance is harmful to marine copepods.

TEST FACILITY Chemex (1998b)

C.2.3. Chronic toxicity to sediment dwelling amphipods

TEST SUBSTANCE	Notified biopolymer
METHOD	Static test conditions according to Paris Commission Guidelines 1994 "A Sediment bioassay using an amphipod *Corophium sp*.
Species	*Corophium volutator*
Exposure Period	10 days
Auxiliary Solvent	None
Analytical Monitoring	Visual
Remarks - Method	A nominal 1000 mg/L stock solution was prepared by adding test substance to natural sea water from Ministry of Agriculture Fisheries and Food Laboratories at Burnham-on-Crouch and shaking vigorously. The stock solution was allowed to stand for 4 hours. The aerobic layer (5-10 cm) of sediment from Sandwich Bay Kent UK, was collected sieved (500 µm), washed and settled. A preliminary study was performed but no details are recorded. From the results of the preliminary study duplicates of 10 Corophium were exposed to nominal concentrations of the test substance prepared by addition of the stock solution to the sediment. A sample of the sediment was dried to determine water content. All missing organisms were presumed dead. pH: 7.4-7.8 Dissolved Oxygen: 92-100% Temperature: 15-17°C Salinity: 34-36‰

RESULTS

Concentration mg/kg		*Number of Arcatia Tonsa*	*Mortalities*
Wet	*Dry*		*10 days*
0	0	20	2
1 000	1 282	20	2
1 800	2 308	20	1
3 200	4 103	20	2
5 600	7 179	20	2
10 000	12 821	20	3

LC50	> 12821 mg/kg dry sediment
NOEC	12821 mg/kg dry sediment
Remarks - Results	The stock solution was dark reddish in appearance, with no other observations recorded. The water content of the sediment was 22%. The temperature was outside of the recommended limit at certain times but is not expected to have affected the results.
CONCLUSION	The test substance is practically non-toxic to Corophium.
TEST FACILITY	Chemex (1998c)

C.2.4. Algal growth inhibition test

TEST SUBSTANCE	Notified biopolymer
METHOD	Static test conditions according to ISO draft method (1991) Water Quality Marine algal growth inhibition test with *Skeletonema costatum* and *Phaeodactylum tricornutum* (ISO/DIS 10253)
Species	*Skeletonema costatum*
Exposure Period	72 hours
Concentration Range	Nominal: 1.0-15.8 mg/L

	Actual: Not measured
Auxiliary Solvent	None
Water Hardness	Not reported (natural sea water)
Analytical Monitoring	Haemocytometer and microscope
Remarks - Method	A nominal 1000 mg/L stock solution was prepared by adding test substance to filtered and sterilised natural sea water. The stock solution was allowed to stand for 1 hour. Algal cells of initial concentration of ~ 1×10^4 cells/mL were subjected to triplicate test solutions of 1.0, 2.0, 4.0, 7.9 and 15.8 mg/L and a control. Temperature: 20±1°C Light: continuous white light 6000-10000 Lux. pH: 7.7-8.2

RESULTS

Biomass		*Growth*	
EbC50 mg/L at 72 hours	*EbC50 mg/L at 48 hours*	*ErC50 mg/L at 72 hours*	*ErC50 mg/L at 48 hours*
<1.0	<1.0	2.15	1

Remarks - Results	The stock solution was dark reddish in appearance, with no other observations recorded. The cell density in the control increased by a factor of 68. The growth curves for 1 and 2 mg/L solutions at 24 hours showed that the algal growth was delayed but subsequent growth occurred. This may account for the lower ErC50 value for 48 hours than at 72 hours. However, due to the very low cell count at 24 hours, it is difficult to draw a meaningful conclusion. The test substance is coloured and the light shielding effect may have contributed to the toxicity of the test substance. However, without further definitive testing the inherent toxicity of the test substance cannot be differentiated from the light shielding effect.
CONCLUSION	The test substance is toxic to algae.
TEST FACILITY	Chemex (1998d)

C.2.5. *Lemna* growth inhibition test

TEST SUBSTANCE	Notified biopolymer
METHOD	Draft OECD Guideline "Lemna Growth Inhibition Test April 2004". Semi-Static Test.
Species	*Lemna minor*
Exposure Period	7 days
Concentration Range	Nominal: 0.10-1000 mg/L Actual: Not measured
Auxiliary Solvent	None
Water Hardness	Not reported.
Analytical Monitoring	Visual; Mass
Remarks - Method	A nominal 100 mg/L stock solution was prepared by adding test substance to the culture medium. A range finding test was conducted by subjecting duplicate samples of 3 colonies (9 fronds) to test concentrations of 0.10, 1.0, 10, 100 mg/L and a control for 7 days. The test solutions were renewed on days 3 and 5. On the basis of the results of the range finding test a limit test was conducted. A nominal 1000 mg/L solution was prepared by adding test substance to the culture medium. Six

replicates of 3 colonies (9 fronds) were subjected to the test concentration for 7 days. A control was run in triplicate. The solutions were renewed on day 3 and 5. Observations were made on days 3, 5 and 7; and the dry weight of the fronds were measured at the end of the test (day 7). A positive control using 3,5-dichlorophenol (0.625, 1.25, 2.5, 5.0, 10 mg/L) was run not more than 6 months prior to the current test. Spectrophotometric measurements of the 1000 mg/L solution were taken at wavelengths required for photosynthesis (460 and 665 nm).

RESULTS

Biomass (Yield)		*Growth*	
EbC50 Frond No. mg/L at 72 hours	*EbC50 Dry Weight mg/L at 48 hours*	*ErC50 Frond No. mg/L at 72 hours*	*ErC50Dry Weight mg/L at 48 hours*
>1000	>1000	>1000	>1000

Remarks - Results

No remarkable observations were recorded for any of test solutions. The absorbance for the two wavelengths (460 and 665 nm) was 1.794 and 0.223 respectively. This showed significant absorbance in the wavelength required for photosynthesis. However, *lemna* grows on the surface of water and is therefore less susceptible to the light shielding effect of coloured substances than other aquatic plant organisms. All fronds in the test were green with no remarkable observations recorded. The positive control had an EbC50 based on yield by frond number and dry weight of 2.1 and 2.0 mg/L respectively; and an ErC50 by growth rate by frond number and dry weight of 2.8 and 2.4 mg/L respectively.

CONCLUSION

The test substance is practically non-toxic to the aquatic plant *lemna*.

TEST FACILITY

Safepharm (2006)

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