

File No: STD/1495

May 2014

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Polymer in Tuned Spacer III and Tuned Spacer E+

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 conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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

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

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**Director
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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1495	Halliburton Australia Pty Ltd	Polymer in Tuned Spacer III and Tuned Spacer E+	ND*	< 15 tonnes per annum	Component for gas and oil well drilling

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the aquatic environment.

Recommendations

REGULATORY CONTROLS

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent 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 polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

- (1) Under Section 64(1) of the Act; if
 - The notified polymer is proposed to be used for hydraulic fracturing applications.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component for gas and oil well drilling, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

(Material) Safety Data Sheet

The (M)SDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

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

NOTIFICATION CATEGORY

Standard: Biopolymer (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, molecular weight, polymer constituents, use details, import volume and analogue details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints, acute dermal toxicity, skin irritation, skin sensitisation, repeated dose toxicity, induction of point mutation, genotoxic damage *in vivo* and chromosome damage *in vitro*

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT

None

NOTIFICATION IN OTHER COUNTRIES

Canada, China, Korea, New Zealand and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Tuned Spacer III (product containing 1-5% notified polymer)
Tuned Spacer E+ (product containing 5-10% notified polymer)

MOLECULAR WEIGHT

> 70,000 Da

3. COMPOSITION

DEGREE OF PURITY

> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white to tan powder

Property	Value	Data Source/Justification
Melting Point	Not determined	Varies according to metal salt composition
Boiling Point	Not determined	Expected to be high based on the high molecular weight
Density	Not determined	Estimated to be 1,500 kg/m ³ based on similar compounds
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight
Water Solubility	Not determined	Expected to be soluble in water based on its predominantly hydrophilic functionalities
Hydrolysis as a Function of pH	Not determined	Expected to be hydrolytically stable at the environmental pH range (pH 4 – 9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to water phase as the notified polymer is water soluble
Adsorption/Desorption	Not determined	Expected to partition from water to soil, sludge or sediment based on its very high molecular weight

Dissociation Constant	Not determined	The notified polymer is a salt and is ionised in this form
Particle Size	Not determined	Expected to contain inhalable and respirable fractions
Flammability	Not determined	Not expected to be highly flammable
Autoignition Temperature	> 200 °C	(M)SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to be stable under normal conditions of use. The (M)SDS of the notified polymer states that it can contain sufficient fines to cause a combustible dust explosion.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported in products at concentrations of 1-5% (for Tuned Spacer III) and 5-10% (for Tuned Spacer E+), respectively.

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

Year	1	2	3	4	5
Tonnes	< 15	< 15	< 15	< 15	< 15

PORT OF ENTRY

Adelaide, Melbourne, Perth, Brisbane and Darwin

IDENTITY OF RECIPIENT

Halliburton Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The products containing the notified polymer will be imported in 40-50 lb (18.14-22.68 kg) sacks in shrink-wrapped pallets. The products will be transported by truck to on-shore drilling sites or by a combination of truck and ship to off-shore drilling sites.

USE

The imported products, Tuned Spacer III and Tuned Spacer E+, containing the notified polymer at 1-5% and 5-10%, respectively, will be used as a component for gas and oil well drilling operations. The products will be mixed with water and used to displace drilling fluids/drilling muds and to erode the filter cake from the well formation.

OPERATION DESCRIPTION

The majority (approximately 60% of the total import volume) of the use of the products containing the notified polymer will occur off-shore. The shrink-wrapped pallets of the products packaged in sacks will typically be handled by cranes, forklifts or hoists. The pallets will be unpacked and the sacks of the products containing the notified polymer will be transferred into mixing pits (offshore), batch mixers (onshore/offshore), or tanks (onshore). The products will be immediately mixed with seawater or freshwater depending on the location of the well. The mixing operations will be performed in well ventilated areas, mainly outdoors. The viscous mixture usually containing < 4% of the notified polymer will then be pumped into the wells to displace the drilling fluids/drilling muds during cementing operations. The mixture may be retrieved after the cementing.

When the mixture containing the notified polymer is retrieved, the notified polymer will be at a concentration of < 4% in the recovered slurry and will be segregated as much as possible using a closed loop system. The retrieved mixture containing the notified polymer may be recycled or re-used when possible.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Cement Engineer	3	24-36
Mud Engineer	3	24-36

EXPOSURE DETAILS

Exposure of workers to the notified polymer during transport and storage will only occur in the event of an accidental release.

Dermal, ocular and inhalation exposure to the solid (dust) form of the notified polymer (at up to 10% concentration) may occur during transferring and mixing the products containing the notified polymer with water in the pits or tanks at the well sites, prior to pumping the mixture down the well. Dermal and ocular exposure to the notified polymer at concentrations < 4% may occur when handling the mixture containing the notified polymer during the well operations, including transfer, retrieval and disposal of un-used or recycled materials. It is expected that workers will wear PPE including impervious rubber gloves, protective clothing, chemical goggles and respiratory protection to reduce the potential for exposure. The open air environment at the well sites will further reduce the likelihood of exposure.

According to the MSDS of the products containing the notified polymer, the products also contain crystalline silica which is known to cause serious harm to human health by inhalation. The MSDS recommends the use of a NIOSH certified, European Standard EN 149 or equivalent respirator when handling the products. The protective measures taken to prevent workers from exposure to crystalline silica will also reduce the potential for inhalation exposure to the notified polymer.

6.1.2. Public Exposure

The notified polymer will not be available to the public and will only be used by the notifier in highly controlled environments at well operation areas. As such public exposure to the notified polymer is not expected, unless accidental release of the notified polymer occurs during transport.

6.2. Human Health Effects Assessment

Limited toxicity data is available for the notified polymer. Therefore, data for a similar analogue polymer was used to evaluate the potential hazards. Where information for a specific endpoint was unavailable, hazard information for the class of compounds that the notified polymer belongs was evaluated to estimate the toxicological profile of the notified polymer.

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 5.37 mg/L/4 hour; low toxicity
Rabbit, eye irritation	non-irritating

Toxicokinetics, metabolism and distribution

No toxicokinetic information for the notified polymer was provided; however, the absorption, distribution and excretion of an analogue polymer has been studied (WHO). Sprague-Dawley rats were administered by gavage with the ³H/¹⁴C labelled analogue polymer. Results showed that less than 0.55% of the given radioactivity was detected in expired air and the majority (> 90%) of the radioactivity was excreted in faeces and urine. The

radioactivity in tissues (blood, brain, liver, kidney, lung, muscle, skin, heart and carcass) was low and the peak blood level, which was about 0.4% of the administered radioactivity, occurred about 5 hours after dosing.

Acute toxicity

Studies conducted on the notified polymer indicate that the polymer is of low acute toxicity via the oral and inhalation routes.

No data was provided on acute dermal toxicity. Based on the large molecular weight of the notified polymer (> 70,000 Da), absorption of the polymer through the dermal route is expected to be limited.

Irritation and sensitisation

Based on a study conducted in rabbits, the notified polymer is non-irritating to the eye.

Studies were not provided for skin irritation or skin sensitisation for the notified polymer. The notified polymer does not contain any structural alerts for irritation or sensitisation. Furthermore, results from a number of studies conducted on polymers from the same chemical class as the notified polymer were indicative that the notified polymer is unlikely to be irritating or sensitising (CIR, 2012).

Repeated dose toxicity

A repeated dose toxicity study was not provided for the notified polymer.

Repeated oral exposure to the analogue polymer has been studied in mice, rats, monkeys and dogs (WHO). Data on the analogue polymer showed that repeated exposure up to 90 days in rats at levels up to 6% in the diet did not cause any adverse effects. In a 28-day study in monkeys, no obvious signs of toxicity were observed at the highest dose level of 3 g/kg bw/day. In a study in dogs, which were treated for 1 year at dose levels up to 6% in the diet, there were no adverse effects that could be attributed to chronic exposure to the analogue polymer.

Results from a limited study on tolerance to the analogue polymer in humans indicated that oral doses of up to 200 mg/kg bw/day over a 23-day period did not elicit any adverse reactions, although faecal bulking effects were observed in most subjects (WHO).

Based on the available information on the analogue polymer, the toxicity of the notified polymer upon repeated exposure is expected to be low.

Mutagenicity/Genotoxicity

Genotoxicity studies were not provided for the notified polymer.

The genotoxicity of a number of polymers from the same chemical class as the notified polymer have been evaluated *in vitro* using the Ames test, chromosomal aberration assay, and/or DNA repair test, with and without metabolic activation (CIR, 2012). The results were negative, indicative of non-genotoxic properties for the notified polymer.

Carcinogenicity

In long-term carcinogenicity studies, the analogue polymer did not induce any adverse effects in mice or rats at the highest dose levels of 3% or 5% in the diet, respectively (WHO).

Toxicity for reproduction

In reproduction and teratogenicity studies in rats in which the analogue polymer was given at dose levels up to 5% in the diet, there was no evidence of interference with the reproductive process, and no embryotoxic or developmental effects were observed (WHO).

Observations on human exposure

Five female and five male volunteers consumed the analogue polymer at a dose level of 175 mg/kg bw/day for 7 days followed by a dose level of 200 mg/kg bw/day for a further 16 days. Plasma biochemistry parameters, haematological indices, urinalysis parameters, blood glucose and plasma insulin concentrations and breath hydrogen concentrations were monitored during the study. The authors concluded that the ingestion of the analogue polymer at the given dose levels caused no adverse dietary nor physiological effects in any of the volunteers in the study. There were no allergenic nor other subjective untoward manifestations reported by or observed in any of the human subjects. The ingestion of the analogue polymer, at the stated daily intake levels, did not cause adverse toxicological effects (WHO).

Health hazard classification

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

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety**

Available data on the notified polymer and analogous polymers indicate that the notified polymer is of low hazard. The notified polymer is likely to contain respirable particles; however lung overloading effects are not expected as the notified polymer is water soluble and is expected to be readily cleared from the lungs. Furthermore, given the relatively low use concentration (up to 10%) of the notified polymer and control measures in place to limit exposure to the other hazardous ingredients present in the imported products, exposure to the notified polymer under the proposed use is expected to be low.

Therefore, based on the expected low hazard of the notified polymer, low use concentration and control measures in place to limit exposure to other hazardous ingredients present in the imported products, the risk of the notified polymer to workers is not considered to be unreasonable.

6.3.2. Public Health

As the notified polymer will not be available to the public, public exposure is not expected except for accidental release of the notified polymer during transport. Based on proposed use scenarios, the risk of the notified polymer to the public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS**7.1. Environmental Exposure & Fate Assessment****7.1.1. Environmental Exposure****RELEASE OF CHEMICAL AT SITE**

The notified polymer will be imported into Australia as finished products and releases of the notified polymer to the environment are not expected from manufacture and reformulation. Accidental spills of the notified polymer during import, transport or storage are expected to be adsorbed onto a suitable material and collected for disposal in accordance with local regulations. Small amounts of the notified polymer may remain as residues in empty containers, which are expected to be disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used between drilling and cementing steps during gas and oil well installation for both onshore (40% of the total import volume) and offshore applications (60% of the total import volume). In the oilfield, the products containing the notified polymer will be mixed with water and pumped into wells to displace drilling fluids/mud and to erode the filter cake from the well formation. The mixture containing the notified polymer will either remain in the well during the well completion phase and be pumped out with the mud systems, or will be pumped out before cementing operations and be collected for reuse and/or disposal.

RELEASE OF CHEMICAL FROM DISPOSAL

As the notified polymer is used in aqueous solution to displace the drilling fluid/drilling mud during the cementing of oil and gas, the majority of the notified polymer is expected to be incorporated into the bulk drilling fluid and be disposed of along with the drilling mud. After the completion of drilling operations, the drilling mud containing the notified polymer is expected to be pumped out for disposal, recycling or reuse.

For onshore operations, if the drilling mud cannot be re-used, it is expected to be sent to a registered disposal facility for oil-based mud or tailing dam for water-based mud. If the mud can be reused, it will be treated to recondition the drilling fluids. Solids generated during reconditioning of the drilling fluids will be sent to a registered disposal facility, which most likely entails landfill disposal of the notified polymer. Therefore, significant release of the notified polymer to aquatic compartment from onshore operations is not expected.

For offshore operations, the drilling mud is expected to be released directly to the ocean if it cannot be re-used. If oil retention is above the permission level for being disposed of to the ocean, the oil-based mud is expected to be

disposed of at a registered disposal facility. If the drilling mud is reconditioned, solids generated during reconditioning of the drilling fluid will be disposed of to the ocean.

7.1.2. Environmental Fate

The notified polymer is not expected to persist in the environment as it was measured to be readily biodegradable (84% biodegradation over 28 days). For the details of the environmental fate study please refer to Appendix C.

In most circumstances, the notified polymer will be incorporated into the bulk drilling fluid and share the fate of the drilling mud. The mud systems will be pumped out for disposal, recycling or reuse after the completion of drilling operations.

If the drilling mud is re-used, water and oil-based mud will be treated to recondition the drilling fluids. Solids generated from drilling fluid reconditioning will be sent to a registered disposal facility for onshore applications and to the ocean for offshore applications.

If the drilling mud cannot be re-used, for onshore applications, oil-based mud will be disposed of at a registered disposal facility and water-based mud will be discharged to a tailing dam. The notified polymer is expected to adsorb to sludge and sediment, and degrade in the tailing dam. Sludge and sediment containing the notified polymer will be disposed of at a registered disposal facility, which most likely entails landfill disposal of the notified polymer. For offshore operations, water-based mud and oil-based mud, if oil retention is below the permission level, will be disposed of directly to the ocean. If oil retention is above the permission level, oil-based mud would be sent to a disposal facility.

Notified polymer disposed of to landfill is not expected to be mobile based on its very high molecular weight and ionic properties. Notified polymer disposed of to water systems is expected to disperse and degrade. Based on its high water solubility and molecular weight, the notified polymer is not expected to bioaccumulate. The notified polymer is expected to ultimately degrade via biotic or abiotic pathways in land or water to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

It was indicated by the notifier that up to 60% of the total import volume of the notified polymer will be used offshore as cementing chemical between drilling and cementing operations of oil and gas wells. As direct discharge of the notified polymer into seawater is likely from offshore use, the Predicted Environmental Concentration in seawater (PEC_{water}) has been calculated based on the CHARM model (Thatcher et al., 2005). Based on the CHARM model, discharges of spacer fluid and mixwater have been identified as the main routes for polymer release in cementing operations. Both spacer fluids and mixwater are discharged in batches and the greatest effect will occur within a radius (r) of 500 m from the discharge line. Assuming that none of the polymer is depleted or transformed between addition and discharge, the discharge concentration equals to the initial concentration (dosage, mg/L). For the worst case scenario, the PEC_{water} in the water column due to mixwater discharge is calculated using following equation:

$$PEC_{water} = C_{i,mixwater} \times D_{batch,mixwater}$$

In this relationship,

PEC_{water} = Predicted Environmental Concentration in the water column (mg/L);

C_i = Initial concentration of the notified polymer in mixwater (dosage; mg/L);

$D_{batch,mixwater}$ = Batchwise dilution factor of mixwater (-).

The notifier indicated that the spacer fluid will be prepared by mixing 60% water with 40% product (containing up to 10% of the notified polymer). Therefore, the initial dosage of the notified polymer in mixwater is up to 4% (= 40% × 10%). As the mixwater contains only up to 4% of the notified polymer, it is reasonable to assume a density of 1 kg/L, i.e. the density for water, for the mixwater. Therefore, the original dose for the notified polymer in mixwater is calculated to be 40 g/L. The default dilution factor is set at 2.2×10^{-5} in the CHARM model under the batch-wise discharge scenario (Thatcher et al., 2005, p. 49).

Therefore, the resulting PEC_{water} is calculated to be:

$$PEC_{water} = C_{i,mixwater} \times D_{batch,mixwater} = 40 \text{ g/L} \times 2.2 \times 10^{-5} = 88 \times 10^{-5} \text{ g/L} = 880 \mu\text{g/L}$$

The PEC_{sediment} for a batch-wise discharge scenario is not calculated in the CHARM model because there is assumed to be insufficient time to allow the establishment of equilibrium between the high short-term levels of polymer in the water column arising from batch-wise release of mud and the levels of the polymer in sediments near the discharge point. Furthermore, as the notified polymer is highly water soluble and is expected to readily disperse and biodegrade in the aqueous compartment, it is not expected to reach ecotoxicologically significant concentrations in the sediment compartment. Therefore, the PEC_{sediment} has not been calculated for this assessment.

7.2. Environmental Effects Assessment

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

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	96 hours $LC50 > 125$ mg/L	Not harmful to fish
Marine invertebrates	48 hours $EC50 = 126$ mg/L	Not harmful to marine aquatic invertebrates
Algal Toxicity	72 hours $E_rC50 = 1,240$ mg/L (full study report not available)	Not harmful to algae
Mysid Shrimp	96 hours $LC50 = 75,000$ mg/L (full study report not available)	Not harmful to shrimp

Based on the endpoints for toxicity of the notified polymer to aquatic organisms, the notified polymer is not considered to be harmful to aquatic organisms under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Therefore, the notified polymer is not formally classified under the GHS.

Based on its measured acute toxicity, biodegradability and expected low bioaccumulation potential, the notified polymer is not formally classified under the GHS for the chronic hazard.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) for the notified polymer has been calculated and is presented in the table below. The PNEC is calculated based on the endpoint for the most sensitive species for the notified polymer (*A. Tonsa*, 48 hours $EC50 = 126$ mg/L) and an assessment factor of 100. An assessment factor of 100 has been used as acute toxicity endpoints for three trophic levels are available. Although the full study report for algal ecotoxicity is not available, the available ecotoxicity endpoints indicate that marine invertebrates represent the sensitive species.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (<i>A. Tonsa</i>)	126	mg/L
Assessment Factor	100	
PNEC:	1,260	µg/L

7.3. Environmental Risk Assessment

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - Ocean	880	1,260	0.70

The risk quotient ($Q = PEC/PNEC$) for ocean environment is calculated to be < 1 . Based on its water solubility and high molecular weight, the notified polymer is not expected to bioaccumulate in aquatic organisms. Furthermore, the notified polymer is not expected to persist in the environment. On the basis of $PEC/PNEC$ ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the aquatic environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure
Species/Strain	Rat/Sprague-Dawley (albino)
Vehicle	Corn oil
Remarks - Method	Purity of the test substance was not provided. Only one dose of 5000 mg/kg bw was tested in a group of 10 rats by gavage.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose (mg/kg bw)</i>	<i>Mortality</i>
1	5 M/5 F	5,000	0/10

LD50	> 5,000 mg/kg bw
Signs of Toxicity	No signs of toxicity were noted.
Effects in Organs	No observable gross pathology was noted.
Remarks - Results	No GLP statement was provided. Soft faeces were observed in 2 rats at two hours and 5 rats at four hours post-administration.

CONCLUSION	The notified polymer is of low toxicity via the oral route.
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TEST FACILITY	Hazleton (1980a)
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B.2. Acute toxicity – inhalation

TEST SUBSTANCE	Notified polymer
METHOD	Similar to OECD TG 403 Acute Inhalation Toxicity
Species/Strain	Rat/Sprague-Dawley (albino)
Vehicle	Air
Method of Exposure	Whole-body exposure
Exposure Period	4 hours
Physical Form	Solid aerosol (particulate)
Particle Size	> 4.7µm (Samples 1 and 3)
(Mass Median Diameter)	4.6 ± 1.44 µm (Sample 2)
Remarks - Method	Purity of the test substance was not provided. Two groups of rats each consisting of 5 males and 5 females were tested. Group 1 was taken as control and treated with air only.

RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Concentration (mg/L)</i>		<i>Mortality</i>
		<i>Nominal</i>	<i>Actual</i>	
1	5 M/5 F	0	0	0/10
2	5 M/5 F	5.37	0.212	0/10

LC50	> 5.37 mg/L/4 hours
Signs of Toxicity	No signs of toxicity were noted.
Effects in Organs	Kidney discoloration and pitted areas were noted in 4 rats treated with the test substance.
Remarks - Results	No GLP statement was provided. Excessive preening and accumulation of dust on the fur were observed after the animals were exposed to the test substance. No test substance related histopathological alterations in the tissues were noted. Spontaneously occurring lesions were essentially of

equal severity and frequency in treated and control groups.

CONCLUSION The notified polymer is of low toxicity via inhalation.

TEST FACILITY Hazleton (1980b)

B.3. Irritation – eye

TEST SUBSTANCE Notified polymer

METHOD Similar to OECD TG 405 Acute Eye Irritation/Corrosion

Species/Strain Rabbit/New Zealand White

Number of Animals Unwashed 3 M/3 F

Washed 2 M/1 F

Observation Period 7 days

Remarks - Method Purity of the test substance was not provided.

RESULTS

Unwashed

<i>Lesion</i>	<i>Mean Score*</i>	<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
<i>Conjunctiva: redness</i>	0.39	1	< 72 h	0
<i>Conjunctiva: chemosis</i>	0	0	N/A	0
<i>Conjunctiva: discharge</i>	0	0	N/A	0
<i>Corneal opacity</i>	0	0	N/A	0
<i>Iridial inflammation</i>	0	0	N/A	0

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

Washed

<i>Lesion</i>	<i>Mean Score*</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	<i>Animal No.</i>					
	1	2	3			
<i>Conjunctiva: redness</i>	0.3	0	0	1	< 48 h	0
<i>Conjunctiva: chemosis</i>	0	0	0	0	N/A	0
<i>Conjunctiva: discharge</i>	0	0	0	0	N/A	0
<i>Corneal opacity</i>	0	0	0	0	N/A	0
<i>Iridial inflammation</i>	0	0	0	0	N/A	0

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

Remarks - Results No GLP statement was provided. Slight conjunctival redness was noted in five unwashed animals and one washed animal. All signs of irritation were resolved by the 72-hour observation period. One animal in unwashed group was found dead of incidental causes after the 24 h observation and was replaced subsequently replaced. At the 24 h observation, this animal was noted to have iritis and conjunctival redness, chemosis and discharge.

CONCLUSION The notified polymer is non-irritating to the eye.

TEST FACILITY Hazleton (1980c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Product containing the notified polymer (57%)
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Inoculum	Activated sludge
Exposure Period	28
Auxiliary Solvent	None
Analytical Monitoring	Dissolved inorganic carbon measurement using UV-persulfate analyser
Remarks - Method	Tested in accordance with the test guideline without significant deviation from the protocol. Good Laboratory Practices (GLP) were followed.

RESULTS

<i>Test substance</i>		<i>Sodium acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
0	0	0	0
7	62	7	64
14	80	14	77
21	82	21	82
28	84	28	83

Remarks - Results

The validity criteria for the test were satisfied.

The test substance attained 84% degradation after 28 days and the 10-day window criteria were satisfied. The test substance was considered to be readily biodegradable.

The degradation of toxicity control was 86% over 28 days, implying that the test substance was not toxic to the sewage treatment microorganisms used in the study.

CONCLUSION

The notified polymer is considered to be readily biodegradable

TEST FACILITY

Chemex (2006a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Product containing the notified polymer (57%)
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Semi-Static.
Species	Turbot (<i>Scophthalmus maximus</i>)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Salinity	34 – 35‰
Analytical Monitoring	Total organic carbon (TOC) analysis
Remarks – Method	The test medium was standard synthetic seawater. The tests were carried out at 14°C under semi-static conditions. The test media were renewed every 48 hours.

The definitive limit test was conducted at a nominal concentration of 220 mg/L for the test substance. The test was carried out in accordance to the test guideline above without significant deviation from the protocol. Good Laboratory Practices (GLP) were followed.

RESULTS

Concentration mg/L		Number of Fish	Mortality (%)			
Nominal	Actual		24 h	48 h	72 h	96 h
Control	-	7	0	0	0	0
220	Not determined	7	0	0	0	0

LC50 > 125 mg/L at 96 hours.

NOEC 125 mg/L at 96 hours.

Remarks – Results All validity criteria for the test were satisfied.

The highest test concentration resulting in 0% mortality was determined to be 220 mg/L. The results were based on nominal concentration as the actual concentrations for the test substance were not determined. There were no mortality nor abnormal behaviour fish observed for either the control or the test groups.

The 96 hours LC50 was originally reported to be > 220 mg/L in the test report. However, the test substance contains 57% of the active ingredient. Therefore, the LC50 for the notified polymer was re-calculated based on the percentage of the active ingredient contained in the test substance.

CONCLUSION

The notified polymer is not harmful to marine fish.

TEST FACILITY

Chemex (2006b)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

Product containing the notified polymer (57%)

METHOD

ISO TC147/SC5/WG2 (1990): Water Quality: Determination of acute lethal toxicity to marine copepods (*Copepoda*, *Crustacea*)

Species *Acartia tonsa*

Exposure Period 48 hours

Auxiliary Solvent None

Water Salinity 33‰

Analytical Monitoring Total organic carbon (TOC) analysis

Remarks - Method The test medium was standard synthetic seawater. The tests were carried out at 20 °C under semi-static conditions The test media were renewed every 24 hours.

Samples of the test media was take for TOC analysis at the start of the study and at the end of the 48 hours full test period. These data may give an indication of any microbial growth as depletion of oxygen and increase in TOC may indicate an increase in biomass within the test solutions under incubation conditions.

The test was carried out according the test guideline above without significant deviation from the protocol. Good Laboratory Practices (GLP) were followed.

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	-	20	0	0
10	Not determined	20	0	0
25	Not determined	20	0	0
50	Not determined	20	0	1
100	Not determined	20	0	2

250	Not determined	20	3	8
500	Not determined	20	19	20
EC50	126 mg/L at 48 hours (95 confidence limit: 172 - 287 mg/L)			
NOEC	57 mg/L at 48 hours			
Remarks - Results	<p>All validity criteria for the test were satisfied.</p> <p>The 48 hours NOEC was originally reported to be 100 mg/L by the test report author. However, based on the above results for the test nominal concentrations (effects observed at 50 mg/L and 100 mg/L), it is unclear how this NOEC value was derived. Therefore, the reported NOEC should be treated with caution.</p> <p>The results were based on nominal concentration. The 48 hours EC50 and NOEC were reported by the test author to be 221 mg/L and 100 mg/L. As the test substance contains 57% of the active ingredient, the 48 hours EC50 and NOEC were re-calculated based on the percentage of the active ingredient contained in the test substance.</p> <p>Limited change in TOC indicated no substantial growth of micro-organism or metabolism of the test substance.</p>			
CONCLUSION	The notified polymer is not harmful to marine invertebrates.			
TEST FACILITY	Chemex (2006c)			

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