File No: STD/1545

April 2015

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

# PUBLIC REPORT

## Polymer in MUDPUSH* II Spacer D182, Anti-settling Agent D153 and Liquid Anti-settling Agent D162

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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**
**NICNAS**

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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/1545 | Schlumberger Australia Pty Ltd | Polymer in MUDPUSH* II Spacer D182, Anti-settling Agent D153 and Liquid Anti-settling Agent D162 | ND* | 3 tonnes per annum | Cementing additive in oilfield applications |

*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 the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

**Recommendations**

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during preparation of cement:
  - respiratory protection in case of insufficient ventilation

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

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m$^3$.

- 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

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

**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(2) of the Act; if
- the function or use of the polymer has changed from cementing additive in oilfield applications, 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.

No additional secondary notification conditions are stipulated.

*(Material) Safety Data Sheet*
The (M)SDS of the three 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
Schlumberger Australia Pty Ltd (ABN: 74 002 459 225)
Level 5, 256 St George's Terrace
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, CAS number, molecular and structural formulae, analytical data, degree of purity and use details.

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, hydrolysis as a function of pH, adsorption/desorption, flammability, explosive properties, oxidising properties and all toxicity endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2005), Europe and Japan (1996)

## 2. IDENTITY OF CHEMICAL

MARKETING NAMES
MUDPUSH* II Spacer D182 (mixture containing the notified polymer)
Anti-settling Agent D153 (mixture containing the notified polymer)
Liquid Anti-settling Agent D162 (mixture containing the notified polymer)

OTHER NAME(S)
Polysaccharide biopolymer

MOLECULAR WEIGHT
The molecular weight of the notified polymer could not be determined by GPC due to the lack of a suitable solvent. The notifier has stated that they expect the molecular weight to be above 10,000,000 Da.

ANALYTICAL DATA
Reference IR spectra was provided.

## 3. COMPOSITION

DEGREE OF PURITY
> 80%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: beige or grey powder

| Property | Value | Data Source/Justification |
|---|---|---|
| Melting Point/Freezing Point | Not determined | Solid at room temperature |
| Boiling Point | Not determined | Expected to decompose prior to boiling due to the high molecular weight. |
| Density | 820 kg/m$^3$ (range 800-1000 kg/m$^3$) | Measured |
| Vapour Pressure | < 1.3 × 10$^{-9}$ kPa | Estimated based on the NAMW > 1,000 Da (US EPA, 2013) |
| Water Solubility | Partially soluble | Measured |
| Hydrolysis as a Function of pH | Not determined | Contains no functional groups susceptible to hydrolysis |
| Partition Coefficient (n-octanol/water) | log Pow < 0 | Estimated based on water solubility |
| Adsorption/Desorption | Not determined | Expected to partition to soil, sludge or sediment based on low solubility and high molecular weight |
| Dissociation Constant | pKa = 3.67 at 25 °C | Calculated using Marvin (Chem Axon) |
| Particle Size | 96.3% < 177 µm | Measured |
| Flash Point | Not determined | Expected to be high based on the low vapour pressure. |
| 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
For full details of tests on physical and chemical properties, refer to Appendix A.

*Reactivity*
The notified polymer is expected to be stable under normal conditions of use.

***Physical hazard classification***
Based on the submitted physico-chemical data depicted in the above table, the notified 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 within Australia. The notified polymer will be imported into Australia in three formulated products at various concentrations: MUDPUSH* II Spacer D182 (33% notified polymer), Anti-settling Agent D153 (10% notified polymer) and Liquid anti-settling Agent D162 (18-25% notified polymer).

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 3 | 3 | 3 | 3 | 3 |

PORT OF ENTRY
Fremantle

IDENTITY OF MANUFACTURER
Shanghai Smart Chemicals Co., Ltd.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported into Australia as a component in three products in containers of various sizes. MUDPUSH* II Spacer D182 will be imported in 4, 12 and 25 kg bags, Anti-settling Agent D153 in 12 kg bags and Liquid Anti-settling Agent D162 in 20 L drums. The products will be transported by road to the warehouse and then by road and or sea to the site of use. No reformulation of the notified polymer will occur in Australia.

USE
The notified polymer will be used in the oil and gas industry in cementing process. It will be used as a spacer fluid (MUDPUSH* II Spacer D182) and as an anti-settling agent (Anti-Settling Agents D53 and D162) in cement fluids.

OPERATION DESCRIPTION
*MUDPUSH* II Spacer D182*
At the site of use MUDPUSH* II Spacer D182 will be mixed with water and antifoam agent to prepare spacer fluid. The mixing will be done under agitation using paddle/impeller and recirculation via centrifugal pumps. Samples will be collected periodically for quality control testing. Once ready, the spacer fluid will be used in cementing.

*Anti-settling Agent D153*
At the site of use Anti-settling Agent D153 will be added via a hopper or jet mixer to ensure a good dispersion to the required amount of water and antifoam agent. The product will be recirculated via centrifugal pump to achieve complete hydration and then the remaining components will be added to prepare cement slurry. The product may also be dry blended with dry cement. Quality control checks will be conducted on the cement slurry prior to use.

*Liquid Anti-settling Agent D162*
At the site of use Liquid Anti-settling Agent D162 will be added directly to the displacement tank via a liquid additive system. Quality control checks will be conducted on the cement slurry prior to use.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

EXPOSURE DETAILS
Transport and storage workers are not expected to be exposed to the notified polymer (at up to 33 % concentration) except in the unlikely event of an accidental release due to a container breach or spill. Potential routes of exposure are dermal, ocular and inhalation.

Cementing workers may be exposed to the notified polymer at up to 33% concentration via the dermal and ocular and inhalation routes during addition of it to the mixing equipment, transfer of cement fluid to the site of use, sampling for quality control and equipment cleaning and maintenance. Exposure is expected to be minimized by using engineering controls including exhaust ventilation and personal protective equipment (PPE) such as impervious gloves, coveralls, respiratory protection and safety glasses or face shields as anticipated by the notifier in the application dossier.

#### 6.1.2. Public Exposure
The notified polymer is intended only for use in the oil and gas industry. Public exposure to the notified polymer is not expected except in the unlikely event of an accident occurring during road transport.

### 6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. The notified polymer is a polysaccharide biopolymer and as such polysaccharide biopolymers such as xanthan gum, gellan gum and rhamsan gum that are structurally similar to the notified biopolymer can be considered suitable analogues for read-across. Published reports on human health effects of xanthan gum (JECFA 1987), gellan gum (JECFA 1991) and rhamsan gum (Hagiwara *et al*. 2010) were provided by the notifier to fill the data gaps for human toxicological endpoints.

*Toxicokinetics, metabolism and distribution.*
No toxicokinetics, metabolism and distribution studies were provided for the notified polymer. For dermal absorption, molecular weights below 100 Da. are favourable for absorption and molecular weights above 500 Da. do not favour absorption, in addition, poor lipophilicity in substances with log P values < 0 will limit penetration into the stratum corneum and hence dermal absorption (ECHA, 2014). Therefore, based on the anticipated very high molecular weight (approximately 10,000,000 Da.) and the expected low partition coefficient (log Pow < 0), bioavailability of the notified polymer is expected to be very low. The analogues xanthan gum and gellan gum were shown to have low absorption across the gastrointestinal tract and this would also be expected for the notified polymer (JECFA 1987; JECFA 1991).

*Acute toxicity.*
No acute toxicity data were provided for the notified polymer. Acute oral toxicity studies using the analogue xanthan gum conducted on mice, rats and dogs reported $LD_{50}$ values of > 1,000 mg/kg bw, > 45,000 mg/kg bw and > 20,000 mg/kg bw respectively. Acute inhalation toxicity study conducted on rats reported an $LD_{50}$ of > 21 mg/L for xanthan gum (JECFA 1987). Similarly, acute toxicity studies on rats using gellan gum reported an $LD_{50}$ of > 5,000 mg/kg bw via the oral route and an $LD_{50}$ of > 5.09 mg/L via inhalation (JECFA 1991).

Based on the analogue data, the notified polymer is expected be of low toxicity via the oral and inhalation routes.

*Irritation and sensitisation.*
No irritation and sensitisation data were provided for the notified polymer. Skin and eye irritation studies conducted on rats and rabbits respectively found xanthan gum to be non-irritating when tested at 1% concentration (JECFA 1987).

Xanthan gum was reported to be non-sensitising in guinea pigs (JECFA 1987). There are no structural alerts for sensitisation present in the notified polymer and thus the notified polymer is not expected to be a skin sensitiser.

Based on the analogue data, the notified polymer is expected to be non-irritating to the skin and the eyes.

*Repeated dose toxicity.*
No repeated dose toxicity data was provided for the notified polymer. Xanthan gum was found to be of low systemic toxicity (NOAEL > 1,000 mg/kg bw/day) in a range of feeding studies of up to 107 weeks duration in rats and dogs (JECFA 1987). Similarly, gellan gum was also found to be of low systemic toxicity when provided in the diets of rats or dogs for durations of up to 104 weeks (JECFA 1991). A 90-day oral toxicity study conducted on rats found rhamsan gum to be of low toxicity with a no observed adverse effect level (NOAEL) of > 3,362 mg/kg bw/day for male rats and > 4,304 mg/kg bw/day for female rats (Hagiwara *et al*. 2010).

Based on the analogue data, the notified polymer is expected to be of low toxicity following repeated exposure.

*Mutagenicity/Genotoxicity.*
No mutagenicity/genotoxicity data was provided for the notified polymer. Gellan gum was reported to be non mutagenic/genotoxic in a range of in vitro studies and in addition no evidence of carcinogenicity was detected in a 104 week feeding study in rats (JECFA 1991). Based on the analogue data, the notified polymer is expected to be non-mutagenic/genotoxic.

*Toxicity for reproduction.*
No reproduction toxicity study was provided for the notified polymer. A three generation study conducted on rats found xanthan gum to be non-toxic when ingested orally in diet at up to 500 mg/kg bw/day (JECFA 1987). Gellan gum fed to rats at concentrations of up to 5% during gestation days 6-15 produced no treatment related developmental effects (JECFA 1991).

***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

Based on studies conducted on analogous polysaccharide biopolymers it is expected that the notified polymer will be of low toxicity. There is a potential for dermal, ocular and perhaps inhalation exposure of workers to the notified polymer at ≤ 33% concentration, during addition of it to the mixing equipment, transfer of cement fluid to the site of use, sampling and equipment cleaning and maintenance. The notifier anticipates that the use of PPE along with good general ventilation will minimize the exposure.

When the notified polymer is imported as a powder inhalation exposure is possible, with 96.3% having a particle size < 177 µm. If inhaled, due to the partial water solubility of the notified polymer, it is expected that they will be readily cleared from the upper respiratory tract through mucociliary action. Small proportions of the notified polymer may reach the lower respiratory tract, but it should still be readily cleared from the lungs unless high levels are inhaled. When high concentrations of the notified polymer are inhaled, it is likely to be cleared from the lungs, but this may be slower and temporary respiratory impairment is possible. The expected use of appropriate respiratory protection and good ventilation by workers when handling the powdered notified polymer should reduce inhalation exposure levels and hence lower the risk of temporary lung overloading. The risk of acute toxic effects following inhalation exposure to the notified polymers is expected to be low based on the low acute inhalation toxicity of analogous polymers.

Overall, considering the expected low hazard and the low exposure to the notified polymer, including the use of PPE and well ventilated environments, the risk to the health of workers from the use of the notified polymer is not considered to be unreasonable.

#### 6.3.2. Public Health

The public is not expected to be exposed to the notified polymer except in an event of an accident during road transport; hence the risk to the public 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 as a component of three finished end-use products for use in off-shore and on-shore drilling, and will not be reformulated in Australia. Therefore, no environmental release is expected from manufacturing or reformulation in Australia. The release of the notified polymer to the environment during import, storage, and transport is also unlikely. Release from residues in storage and shipping containers is expected to be minimal. Spills or accidental release of the products containing the notified polymer are expected to be collected and disposed of by licensed waste management services in accordance with local government regulations, with residues to be flushed with water.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used in cementing processes in off-shore and on-shore well drilling and well formation operations. In off-shore applications, the notified polymer will be mixed into the cement slurry, then pumped directly into drilling wells to form cement casings. Once cured, the notified polymer will be irreversibly bound in the cement matrix and share the fate of the cement.

In on-shore drilling applications, the notified polymer when used as a spacer fluid will be rehydrated, and then pumped directly into drilling 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 disposal. The notified polymer when used as an anti-settling agent will be mixed into the cement slurry and pumped directly into drilling wells. Once cured, the notified polymer will be irreversibly bound in the cement matrix and share the fate of the cement.

RELEASE OF CHEMICAL FROM DISPOSAL

As the notified polymer will be used in cement slurries for well formation in off-shore and on-shore drilling operations, the majority of the notified polymer will be incorporated into the cement casings and become permanent fixtures. For off-shore applications, the notified polymer in cement slurry will be pumped directly into drilling wells of hundreds to thousands of metres in depth and remain bound within the cement matrix. For on-shore applications, notified polymer in any residual cement spacer fluid returning to the surface will be

collected and extracted by suction for disposal as a hazardous material in accordance with local government regulations.

### 7.1.2. Environmental Fate

The notified polymer is readily biodegradable (89% in 28 days) and is not expected to persist in the environment. For the details of the environmental fate study, please refer to Appendix B.

Under most circumstances, the majority of the notified polymer will be incorporated into cement slurry and once cured, be irreversibly bound into the cement matrix and share the fate of the cement. For off-shore drilling applications, the notified polymer in the cement slurry will be pumped deep into the seabed to form cement casings for drilling wells, and is not expected to be bioavailable. For on-shore applications, the notified polymer in spacer fluid will share the fate of the drilling mud, which will be pumped out for disposal. The notified polymer in cement slurries will be irreversibly bound into the cement matrix and is not expected to be bioavailable.

Notified polymer disposed of to landfill as waste is not expected to be mobile based on its very high molecular weight and low water solubility. Notified polymer released to the aquatic compartment as waste water or wash water is expected to disperse and degrade. Based on its very high molecular weight, low water solubility and ready biodegradability, the notified polymer is not expected to bioaccumulate. The notified polymer is expected to ultimately degrade via abiotic and biotic pathways in landfill or surface waters to form water and oxides of carbon.

### 7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for off-shore and on-shore cementing use patterns since no significant release of the notified polymer to the aquatic environment is expected. The PEC for equipment cleaning and accidental spill clean-up was calculated using a conservative worst case scenario, where the total annual import volume is released to sewer over 260 working days per year across the nation, with no removal within sewage treatment plants (STPs).

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | 3000 | kg/year |
| Proportion expected to be released to sewer | 100% | |
| Annual quantity of polymer released to sewer | 3000 | kg/year |
| Days per year where release occurs | 260 | days/year |
| Daily polymer release: | 11.54 | kg/day |
| Water use | 200.0 | L/person/day |
| Population of Australia (Millions) | 22.613 | million |
| Removal within STP | 0% | |
| Daily effluent production: | 4,523 | ML |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River: | 2.55 | µg/L |
| PEC - Ocean: | 0.255 | µg/L |

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/$m^2$/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/$m^3$). Using these assumptions, irrigation with a concentration of 2.55 µg/L may potentially result in a soil concentration of approximately 17 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 85 µg/kg and 170 µg/kg, respectively.

## 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 B.

| *Endpoint* | *Result* | *Assessment Conclusion* |
|---|---|---|
| Marine Fish Toxicity | 96 h LL50 > 200 mg/L (WAF*)<br>96 h NOEL = 200 mg/L (WAF*) | Not harmful up to the limit of solubility |

| | | |
|---|---|---|
| Marine Copepod Toxicity | 48 h EL50 = 207 mg/L (WAF*)<br>48 h NOEL = 100 mg/L (WAF*) | Not harmful up to the limit of solubility |
| Marine Algal Toxicity | 72 h ErL50 = 828 mg/L (WAF*) | Not harmful up to the limit of solubility |
| Marine Sediment Re-worker Toxicity | 10 d LC50 > 1000 mg/kg (dry wt of sediment) | Not harmful to sediment re-workers |

* WAF: Water Accommodated Fraction

Classification should be based only on toxic responses observed in the soluble range. The ecotoxicity endpoints for the notified polymer are much higher than its solubility limit. No significant adverse effects were observed in any of the provided tests. It is concluded that the notified polymer is not expected to be harmful to organisms in either the aquatic or soil compartments up to the limit of its solubility in water. Therefore, based on its measured acute toxicity, biodegradability, and low bioaccumulation potential, the notified polymer is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic effects.

### 7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for marine invertebrates. A safety factor of 100 was used given endpoints for three trophic levels are available.

| Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment | | |
|---|---|---|
| NOEL (copepod) | 100 | mg/L |
| Assessment Factor | 100 | |
| Mitigation Factor | 1.00 | |
| PNEC: | 1000 | µg/L |

## 7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

| Risk Assessment | PEC µg/L | PNEC µg/L | Q |
|---|---|---|---|
| Q - River | 2.55 | 1000 | 0.003 |
| Q - Ocean | 0.255 | 1000 | < 0.001 |

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Based on its high molecular weight and ready biodegradability, the notified polymer is not expected to be persistent in the environment, nor bioaccumulate in aquatic organisms.

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

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Density** 820 kg/m$^3$

| | |
|---|---|
| Method | Not specified |
| Remarks | The product specification is for a bulk powder density of 800 – 1000 kg/m$^3$. |
| Test Facility | Shanghai Smart Chemicals Co., Ltd. |

**Water Solubility** Partially soluble

| | |
|---|---|
| Method | Not specified. |
| Remarks | In-house method. Grains showed signs of swelling. |
| Test Facility | M-I SWACO (2010d) |

**Particle Size** 96.3% < 177 µm

| | |
|---|---|
| Method | Not specified |
| Remarks | The product specification is for 95% of the notified polymer to pass 80 mesh (177 µm). |
| Test Facility | Shanghai Smart Chemicals Co., Ltd. |

# APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

## B.1. Environmental Fate

### B.1.1. Ready biodegradability

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 306 Biodegradability in Seawater: Closed Bottle Test |
| Inoculum | Natural fauna of microorganisms in aerated aged seawater collected from a marine station (Bergen, Germany). |
| Exposure Period | 28 days |
| Auxiliary Solvent | None |
| Analytical Monitoring | Chemical Oxygen Demand (COD) |
| Remarks - Method | No significant deviation in protocol |

RESULTS

| *Test substance* | | *Sodium benzoate* | |
|---|---|---|---|
| *Day* | *% Degradation* | *Day* | *% Degradation* |
| 0 | 0 | 0 | 0 |
| 7 | 33 | 7 | 60 |
| 14 | 55 | 14 | 60 |
| 21 | 73 | 21 | 62 |
| 28 | 89 | 28 | 71 |

| | |
|---|---|
| Remarks - Results | All validity criteria for the test were satisfied. The respiration blank (maximum of 12%) did not exceed the threshold level of 30% biodegradation, indicating the stability of basal microbial respiration. The percentage degradation of the reference compound, sodium benzoate, attained the threshold level of 60% by 14 days. Therefore, the test indicates the suitability of the inoculums. The inhibition test attained 84% biodegradation by 28 days, showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the notified polymer after 28 days was 89%. Therefore, the test substance is classified as readily biodegradable according to the OECD (306) guideline. |
| CONCLUSION | The notified polymer is readily biodegradable. |
| TEST FACILITY | M-I SWACO (2010e) |

## B.2. Ecotoxicological Investigations

### B.2.1. Acute toxicity to fish

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OSPAR Protocol on Methods for the Testing of Chemicals used in the Offshore Oil Industry, SOP 39 – Semi-static. |
| Species | *Cyprinodon variegatus* (Sheepshead minnow) |
| Exposure Period | 96 hours |
| Auxiliary Solvent | None |
| Analytical Monitoring | No analytical verification of the test substance concentrations. |
| Remarks – Method | For the observation test, the notified polymer was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. Following the observation test (conducted at a nominal concentration of 200 mg/L of the notified polymer), a reference test to determine the validity of the results was conducted at a low concentration of 1.3 mg/L and a high concentration of 3.3 mg/L of the notified polymer due to its low water solubility. The test results are considered valid if ≤ 20% mortality is |

attained at the low concentration, and ≥ 80% mortality is attained at the high concentration. No significant deviation in protocol.

RESULTS

| *Test type* | *Concentration mg/L* | | *Number of Fish* | *Mortality (%)* | | | | |
|---|---|---|---|---|---|---|---|---|
| | *Nominal* | *Actual* | | *0 h* | *24 h* | *48 h* | *72 h* | *96 h* |
| Observation | Control | Control | 10 | 0 | 10 | 20 | 20 | 20 |
| | 200* | 2.3 | 10 | 0 | 0 | 0 | 0 | 0 |
| Reference | Control | Control | 10 | 0 | 0 | 0 | 10 | 10 |
| | 'low' | 1.3 | 10 | 0 | 0 | 0 | 10 | 10 |
| | 'high' | 3.3 | 10 | 0 | 100 | 100 | 100 | 100 |

* WAF: Water Accommodated Fraction

| | |
|---|---|
| LL50 | > 200 mg/L (WAF) at 96 hours |
| NOEL | 200 mg/L (WAF) at 96 hours |
| Remarks – Results | A high percentage of mortality occurred in the control cohort (20%) in the observation test, however, this was not deemed to have had a significant impact on the validity or the integrity of the study. The results of the reference test indicated the validity of the observation test results. All other validity criteria were met and satisfied. The actual concentration of the notified polymer in WAFs was measured at 96 hours at the end of the test period. The test solutions were renewed after 48 hours during the test period. The 96 h LL50 for fish was determined to be > 200 mg/L, and the corresponding 96 h NOEL was determined to be 200 mg/L, based on measured concentrations. |
| CONCLUSION | Under the study conditions, the notified polymer is not harmful to marine fish up to the limit of its water solubility. |
| TEST FACILITY | M-I SWACO (2010f) |

**B.2.2. Acute toxicity to aquatic invertebrates**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | ISO 14669:1999, SOP 31 – Static |
| Species | *Arcatia tonsa* (marine copepod) |
| Exposure Period | 48 hours |
| Auxiliary Solvent | None |
| Analytical Monitoring | No analytical verification of the test substance concentrations. |
| Remarks - Method | The notified polymer was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. Following the preliminary test (conducted at a nominal concentration of 100 mg/L of the notified polymer), the definitive test was conducted at nominal concentrations of 50-1000 mg/L of the notified polymer due to its low water solubility. No significant deviation in protocol. |

RESULTS

| *Concentration mg/L* | | *Number of Copepods* | *Cumulative Immobilised (%)* | |
|---|---|---|---|---|
| *Nominal* | *Actual* | | *24 h* | *48 h* |
| Control | Control | 20 | 0 | 0 |
| 50 | — | 20 | 0 | 0 |
| 100 | — | 20 | 0 | 0 |
| 178 | — | 20 | 10 | 35 |
| 317 | — | 20 | 55 | 90 |
| 563 | — | 20 | 100 | 100 |
| 1000 | — | 20 | 95 | 100 |

| | |
|---|---|
| EL50 | 207 mg/L (WAF) at 48 hours |
| NOEL | 100 mg/L (WAF) at 48 hours |
| Remarks - Results | The pH of the test solutions at the two highest concentrations of the notified polymer were lower (pH 7.3-7.4) than the reported pH in the protocol (pH 7.7-8.3), however, this was not deemed to have had a significant impact on the validity or the integrity of the study. The test solutions were not renewed during the 48 h test period. The 48 h EL50 was determined to be 207 mg/L, and the 48 h NOEL was determined to be 100 mg/L, based on measured concentrations. |
| CONCLUSION | Under the study conditions, the notified polymer is not harmful to marine invertebrates up to the limit of its water solubility. |
| TEST FACILITY | M-I SWACO (2010b) |

**B.2.3. Algal growth inhibition test**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | ISO/DP 10253, SOP 30: Water Quality – Marine Algal Growth Inhibition Test |
| Species | *Skeletonema costatum* (marine alga) |
| Exposure Period | 72 hours |
| Concentration Range | Nominal: 100-1000 mg/L (loading rate)<br>Actual: Not determined |
| Auxiliary Solvent | None |
| Analytical Monitoring | No analytical verification of the test substance concentrations. |
| Remarks - Method | The notified polymer was prepared as a Water Accommodated Fraction (WAF) due to its low solubility. The test was conducted at 100, 177, 316, 562, and 1000 mg/L of the notified polymer. No significant deviation in protocol |

RESULTS

| *Biomass* | | *Growth* | |
|---|---|---|---|
| *$E_bL50$*<br>*mg/L at 72 h* | *$NOE_bL$*<br>*mg/L* | *$E_rL50$*<br>*mg/L at 72 h* | *$NOE_rL$*<br>*mg/L* |
| Not determined | Not determined | 828 | Not determined |

| | |
|---|---|
| $E_rL50$ | 828 mg/L (WAF; 95% CL: 643-1202 mg/L) at 72 hours. |
| Remarks - Results | All validity criteria for the test were satisfied. The 72 h ErL50 was calculated to be 828 mg/L (95% CL: 643-1202 mg/L). |
| CONCLUSION | Under the study conditions, the notified polymer is not harmful to marine alga up to the limit of its water solubility. |
| TEST FACILITY | M-I SWACO (2010a) |

**B.2.4. Sediment re-worker test**

| | |
|---|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OSPAR, A Sediment Bioassay Using An Amphipod *Corophium* sp., SOP 32 |
| Species | *Corophium volutator* |
| Exposure Period | 10 days |
| Concentration Range | Nominal: 1154 mg/kg dry weight of sediment |
| Auxiliary Solvent | None |
| Analytical Monitoring | No analytical verification of the test substance concentrations. |
| Remarks - Method | The test organisms were introduced to sediment containing the test |

substance a concentration of 1154 mg/kg (dry wt) and exposed for a period of 10 days in a static test at 14.3-16.7 °C. Two replicates were prepared for the test concentration and four replicates for the control. Test organisms were added to the spiked and control sediments at a density of 10 per vessel. Ambient laboratory lighting was used.

RESULTS

| *Concentration mg/kg dry weight of sediment* | *Total Mortality (%)* |
|---|---|
| Control | 8 |
| 1154 | 10 |

| | |
|---|---|
| LC50 | > 1000 mg/kg (dry wt) at 10 days |
| Remarks - Results | All validity criteria for the test were satisfied. No significant effects were observed. Consequently, the LC50 was determined to be > 1000 mg/kg (dry weight of sediment). |

CONCLUSION Under the study conditions, the notified polymer is not harmful to the sediment re-worker.

TEST FACILITY M-I SWACO (2010c)

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