File No: LTD/1715

May 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in WG-33 Gelling Agent

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
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
LTD/1715	Halliburton Australia Pty Ltd	Chemical in WG-33 Gelling agent	ND*	≤ 1 tonne per annum	Additive for oil and gas well drilling

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer cannot be classified 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.

Environmental risk assessment
On the basis of the PEC/PNEC ratio for off-shore use and the assessed 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 implement the following safe work practices to minimise occupational exposure during handling of products containing the notified polymer:
  - Avoid skin and eye contact

- 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 in finished products:
  - Gloves
  - Coveralls
  - Safety goggles

  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 safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified 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 polymer has a number-average molecular weight of less than 1,000;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from additive for oil and gas 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.

No additional secondary notification conditions are stipulated.

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

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

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

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA-TSCA and Canada-NDSL

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in WG-33 Gelling Agent

ANALYTICAL DATA
Reference GPC spectra were provided.

3. COMPOSITION

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 10,000 Da

DEGREE OF PURITY
> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown to pale green gel.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	140 °C	Analogue data
Boiling Point	Not determined	Expected to decompose around 205 °C based on analogue data
Density*	1,100 kg/m^3 at °C	(M)SDS
Vapour Pressure*	1.72 × 10^{-2} kPa at 20 °C	(M)SDS
Water Solubility	Not determined	Expected to be soluble in water based on the presence of hydrophilic functional groups in the chemical structure and the use in water-based systems.
Hydrolysis as a Function of pH	Not determined	The notified polymer contains functionalities that hydrolyse under strong acidic conditions. However, it is not expected to hydrolyse under normal

		environmental conditions (pH 4–9) and ambient temperature.
Partition Coefficient (n-octanol/water)	Not determined	Not expected to significantly partition to n-octanol as the notified polymer is expected to be water soluble.
Adsorption/Desorption	Not determined	The notified polymer is expected to sorb to sediment/sludge based on its high molecular weight.
Dissociation Constant	Not determined	Contains ionisable functionalities and has potential to ionise under environmental conditions of pH 4–9.
Flash Point*	> 160 °C	(M)SDS
Flammability	Combustible	Analogue data
Autoignition Temperature	420 °C	Analogue data
Explosive Properties	Not determined	Does not contain any functional groups that imply explosive properties.
Oxidising Properties	Not determined	Does not contain any functional groups that imply oxidising properties.

*Data for final product

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 in Australia. The notified polymer will be imported as a component (≤ 60% concentration) of a rigid gel additive for oil and gas well drilling for on- and off-shore use.

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

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

PORT OF ENTRY
Adelaide, Melbourne, Perth, Brisbane and Darwin

TRANSPORTATION AND PACKAGING
The finished product containing the notified polymer will be imported in 5 gallon (18.9 L) pails.

USE
The notified polymer is a component of a rigid gel additive for oil and gas well drilling for both on- and off-shore use. The gel prevents fluid infiltration or loss from boreholes during drilling and work-over operations as well as providing structural support and preventing sloughing off of material.

OPERATION DESCRIPTION
The notified polymer will not be manufactured, reformulated or repackaged within Australia.

The final product containing the notified polymer (at up to 60% concentration) will be mixed in a blender with other components to prepare the treatment mixture for pumping into wells. This will be done in well ventilated outdoor areas. At well completion, the fluid system will be brought back to the surface, reconditioned, and taken to a disposal facility.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Production service supervisors	2	7
Production operators	2	7
Production assistants	2	7

EXPOSURE DETAILS

Transport and storage
Transport and storage workers are expected to only be exposed to the notified polymer in the unlikely event of an accident. In this case, dermal exposure may occur; however, standard clean-up procedures would be in place to minimise worker exposure to the notified polymer.

End use
Workers involved in mixing the product containing the notified polymer (at up to 60% concentration) may experience dermal and ocular exposure. The notifier has stated that the workers are expected to wear PPE such as gloves and goggles to minimise exposure. Operations involving the use of the finished blended products into wells will be performed in well ventilated areas, mostly outdoors. The notifier states that workers are also expected to wear PPE such as gloves, coveralls (or aprons) and goggles. The notified polymer will be used for short durations and of relatively low frequency.

6.1.2. Public Exposure
The notified polymer is only for industrial use. Therefore, public exposure to the notified polymer is not expected.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer. A Cosmetic Ingredient Review report (CIR, 1986) was submitted with analogue polymers (modified cellulose polymers). The analogues polymers have a wide variety of uses in industrial, medicinal, veterinary and cosmetic markets. The typical use reported in cosmetics was up to 5% concentration.

Toxicokinetics
The metabolism of cellulose derivatives has been extensively studied (although all studies were prior to 1976 and are therefore pre-GLP) and it has been shown that these types of polymers pass through the gastrointestinal tract generally unchanged in humans (CIR, 1986). Due to its high molecular weight the notified polymer is not expected to be significantly absorbed through the skin.

Acute toxicity
An analogue of the notified polymer, hydroxyethylcellulose (HEC, CAS No. 9004-62-0), was tested in a rat acute oral toxicity study at doses between 6,834 and 23,070 mg/kg bw. The doses used in the study are considered excessive and adverse effects at this dose may not be relevant. Some hypoactivity and diarrhoea was noted in all groups. However, no deaths or gross pathological changes were observed up to the maximum dose. In addition, numerous other modified cellulose polymers have been demonstrated to have an acute oral LD50 significantly greater than 2,000 mg/kg bw. Based on the limited analogue data the notified polymer is expected to be of low acute oral toxicity.

Hydroxypropylcellulose (HPC) was tested for acute dermal toxicity in rabbits. When 0.8% HPC was administered to the rabbits at a dose of 5,000 mg/kg bw there were no deaths and no signs of irritation observed. HEC was tested for acute inhalation toxicity where 2 rats, 2 mice and 2 guinea pigs were exposed at 0.19 mg/L for 6 h. There were no reported signs of toxicity at this dose level in any animal (CIR, 1986).

Irritation and sensitisation
The Cosmetic Ingredient Review concluded that ocular and skin irritation studies have demonstrated that cellulose derivatives (including HEC) are at most minimally irritating to rabbit eyes and non-irritating to slightly irritating to the skin of rabbits (CIR, 1986). However, the notified chemical is differentiated from the analogues in that one of the monomers used in its manufacture is classified as Skin Corrosion – Category 1B (EU CLP). When incorporated in the polymer it is less than 20% of the polymer and one of the reactive functional groups of the monomer is not present in the notified polymer. Irritation effects from the incorporation of this monomer into the notified polymer cannot be ruled out.

HEC has been tested in a repeated insult patch test (RIPT) assessing dermal sensitisation in humans. Fifty subjects participated in the study and were subjected to applications of 5% or 100% HEC with no reports of irritation or sensitisation (CIR, 1986).

Based on the limited available data the notified polymer may be irritating to the eye or skin.

Repeated dose toxicity
Numerous sub-chronic (90-day) and chronic (2-year) repeated dose studies in rats to HEC and HPC by the oral route have been performed. However, all studies were completed prior to 1976, and are therefore pre-GLP. Rats were fed doses ranging from 90 to 6,000 mg/kg bw/day in the diet. In the longest study 47% of the animals died, but were all attributed to other factors and not the test substance. No evidence of treatment related effects were observed at necropsy in other studies, although some variations in organ weights and organ weight ratios were observed. Based on the limited available data, the notified polymer is not expected to be toxic by the oral route.

Mutagenicity/Genotoxicity
There are no mutagenicity studies for the notified polymer or its analogue, HEC. A number of other modified cellulose polymers have been tested in multiple in vitro or in vivo studies with no evidence of mutagenicity observed (CIR, 1986). Based on the limited available data, the notified polymer is not expected to be genotoxic.

Developmental and reproductive toxicity
A developmental study was conducted via intraperitoneal injections in mice (at 1–4% concentration) with teratological effects determined 19 days after the initial injections during pregnancy. Foetal resorption was significantly increased as were gross visceral and skeletal deformities in offspring (CIR, 1986). Other modified cellulose polymers did not produce any developmental or reproductive effects via the oral route of exposure (CIR, 1986).

The intraperitoneal route is of limited relevance for the notified polymer. Based on the limited evidence available, the notified polymer is not expected to have developmental or reproductive toxicity following oral exposure, although potential effects cannot be ruled out.

Health hazard classification
As no toxicity data were provided, the notified polymer cannot be classified 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
Dermal exposure and potentially ocular exposure to the notified polymer (at up to 60% concentration) may occur during blending of products as well as when pumping into wells. Eye or skin irritation effects following exposure cannot be ruled out. Workers are expected to wear PPE such as gloves and goggles to minimise exposure to the notified polymer. Based on the predicted low toxicity and the assessed use pattern, the risk of the notified polymer to workers is not considered to be unreasonable.

6.3.2. Public Health
The public will not be exposed to the notified polymer. Therefore, 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 a finished end-use gel product (WG-33) at up to 60% concentration and will not be reformulated in Australia. It will be used as a component of a rigid gel additive for oil and gas well digging for both on- and off-shore use. Therefore, no environmental releases are 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, which is expected to be disposed most likely to landfill.

RELEASE OF CHEMICAL FROM USE

As a completion/workover product, WG-33 is an additive that is used to create a gel, which limits the amount of pumped fluid loss into the targeted formation. It flows like a fluid while it is pumped, but once in place, it forms rigid gel.

At a typical job, the imported product will be mixed in a blender with water and other components to ensure it is hydrated and then cross-linked into what is termed a 'gel pill'. The 'gel pill' is then pumped into the wellbore to perform the intended fluid loss control while other operations are performed on the well. The notified polymer as a component of the gel product is the backbone of the gel and is not mobile underground. Upon completion of the operations, the gel is then broken by pumping an acid into the borehole. Once broken, the gel is removed from the well. In a typical job, 200 gallon of WG-33 (or 757 L, equivalent to 757.1 L × 1.1 kg/L (density) × 60% = 500 kg the notified polymer) will be used.

RELEASE OF CHEMICAL FROM DISPOSAL

Upon completion of the well drilling, the water-based fluid system (and the notified polymer) is brought back to the surface. The used fluid system is indicated by the notifier to be collected and transferred to an approved disposal facility. No further details of disposal have been provided. It is noted that direct disposal of used chemicals for off-shore application is a common practice in Australia.

7.1.2. Environmental Fate

The notified polymer is not readily biodegradable. For the details of the environmental fate studies please refer to Appendix A. However, the notified polymer is not expected to have accumulative potential given the high molecular weight of > 1,000 Da.

For off-shore application, most of the notified polymer is expected to be released to the ocean after use. For on-shore application, the notified polymer is expected to be released to landfill. Whist there may be some release to water, it is not expected to be significant. In water or landfill, the notified polymer is expected to be finally decomposed into water and oxides of carbon and phosphorus.

7.1.3. Predicted Environmental Concentration (PEC)

Off-shore use

The notifier indicates that direct discharge of the notified polymer into seawater is unlikely during off-shore use. Considering this is a common practice in Australia, a PEC has been calculated below for the notified polymer using worst case assumptions for a completion/workover chemical using the CHARM model (Thatcher et al., 2005). In the CHARM model, the PEC_{water} is calculated with the assumption that the greatest effect of the chemical will occur within a radius (r) of 500 m from the discharge line. For completion/workover chemicals in seawater resulting from batchwise discharge the PEC_{water} is calculated using the following equations:

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

Using this equation, PEC_{water} is related to the fraction of the released chemical (f_r), the initial concentration of chemical in completion/workover fluid ($C_{i,completion}$) and the batch wise dilution factor of the completion/workover fluid ($D_{batch,complction}$). The fraction released and the default dilution factor is set at 0.1 and 7.1×10^{-5}, respectively for completion/workover fluids (i.e. WG-33 fits into the 'other chemicals' category) in the CHARM model under the batchwise discharge scenario. Under a worst case assumption of no dilution of

product during use and before discharging of the solution, the release concentration can be calculated as a conservative 60% *(i.e.* the highest possible composition of notified polymer in WG-33) or 0.66 kg/L assuming a density of 1.1 kg/L. Thus, the PEC_{water} for the notified polymer is calculated to be 4.7 mg/L (PEC_{water} = 0.1 × 0.66 kg/L × 7.1 × 10^{-5}).

A PEC for the notified polymer in the sediment was not calculated since the notified polymer is water soluble, and is not expected to be significantly adsorbed to the sediment. Batch-wise release of the notified polymer and the low level of concentration in water are expected to result in a low distribution of the notified polymer to sediment.

On-shore use

The notifier indicated that the used fluid will be transferred to an approved disposal facility. According to the notifier the notified polymer will be used during a short period of well operations. This plus the low imported volume, exposure to the ecological system is considered to be minimal. Accidental surface spills that may result from storage or use at the well site are expected to result in negligible or very small release volumes given typical safety measures implemented during on-shore operations (i.e. physical barriers, available means to collect spills) and are most likely disposed of to landfill. The release to freshwater aquatic systems is not expected. Since the toxicity, use volume and exposure risk of the notified polymer are all low, a predicted environmental concentration (PEC) for onshore use was not calculated.

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 A.

Endpoint	*Result (WAF)*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 1,000 mg/L	Not harmful
Aquatic Invertebrates	48 h EC50 > 2,000 mg/L	Not harmful
Algal Toxicity	72 h EC50 = 619.02 mg/L	Not harmful
Amphipods	10 d LC50 > 10,000 mg/kg dry weight	Not harmful

The above data suggest that the notified polymer is not acutely harmful to aquatic organisms. No chronic toxicity data is available. The notified polymer is not considered to be readily biodegradable. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is not expected to be harmful to fish, invertebrates and algae on an acute or long term basis and is not formally classified under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated using the endpoint for the most sensitive trophic level [alga 72 h EC50 = 619.02 mg/L] and an assessment factor of 100 as endpoints for all three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
72 h EC50 for alga	619.02	mg/L
Assessment Factor	100	
PNEC:	6.19	mg/L

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) for off-shore use has been calculated below:

Risk Assessment	PEC mg/L	PNEC mg/L	Q
Q - Ocean:	4.7	6.19	0.75

It is noted that this calculation is based on the conservative assumption of no dilution for the use of the notified polymer solution. In practical use, the solution will be further diluted when mixing with other components before pumping into the wellbore, in which case the Q value is expected to be lower.

The Risk Quotient for on-shore use was not calculated given the PEC has not been calculated.

Based on the assessed use pattern and the expected low toxicity to aquatic organisms, the notified polymer is not expected to pose an unreasonable risk to the seawater and freshwater aquatic environment.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	Aerobic Biodegradation in Seawater using the Closed Bottle Procedure (In accordance with OECD TG 306)
Inoculum	Marine microorganisms
Exposure Period	28 days
Auxiliary Solvent	Not reported
Analytical Monitoring	Not reported
Remarks - Method	The test was conducted according to the guidelines above using good laboratory practice (GLP). No significant deviations from the test guidelines were reported.

RESULTS

Test substance			*Sodium benzoate*	
Day	*% Degradation*		*Day*	*% Degradation*
	7 mg/L	*8 mg/L*		
7	-4.5	-2.4	7	73.8
14	1.0	2.9	14	78.3
28	2.3	1.5	21	78.1

Remarks - Results	All validity criteria for the test were satisfied. The reference compound, sodium benzoate, reached the 60% pass level by day 7 indicating the suitability of the inoculum. The toxicity control exceeded 25% biodegradation within 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degrees of degradation of the notified polymer after the cultivation period were 2.3% at 7 mg/L and 1.5% at 8 mg/L. It did not reach the pass level within the 10-day window. Therefore, the test substance is not classified as readily biodegradable according to the OECD (306) guideline.
CONCLUSION	The notified polymer is not readily biodegradable
TEST FACILITY	STL (2001)

A.2. Ecotoxicological Investigations

A.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	Semi-Static Acute Toxicity Test Following Paris Commission (PARCOM) Method (1995)
Species	Juvenile Turbot (*Scophthalmus maximus*)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Salinity	33.6%
Analytical Monitoring	None reported
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The above stated test guideline is very similar to OECD TG 203. Water Accommodated Fractions (WAFs) containing the test substance for all treatment concentrations were prepared in artificial seawater. The mixture was mixed overnight and following a 4 hour settling period,

supernatant was removed and used as treatment solution.

RESULTS

Nominal Concentration (mg/L)	*Number of Fish*	*Mortality(96 h)*
Control	10	0
100.0	10	0
177.8	10	0
316.2	10	0
562.3	10	0
1000	10	0

LL50	>1,000 mg/L at 96 hours (WAF)
NOEL	≥1,000 mg/L at 96 hours (WAF)
Remarks – Results	All validity criteria for the test were satisfied.

CONCLUSION The notified polymer is not harmful to fish

TEST FACILITY STL (2002a)

A.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified polymer

METHOD ISO 14669:1999 (E) Water Quality – Determination of Acute Lethal Toxicity to Marine Copepods

Species	*Acartia tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Salinity	34.5 g/L
Analytical Monitoring	None reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The above stated test guideline is very similar to OECD TG 202. Water Accommodated Fractions (WAFs) containing the test substance for all treatment concentrations were prepared in artificial seawater. The mixture was mixed overnight and following a 4 hour settling period, supernatant was removed and used as treatment solution. All the treatment concentrations were observed to be clear but the two highest concentrations were appeared cloudy.

RESULTS

Nominal Concentration (mg/L)	*Number of A.tonsa*	*Cumulative % Immobilised 48 h*
Control	20	1
200	20	2
355.6	20	4
632.4	20	10
1124.7	20	7
2000.0	20	6

LL50	> 2,000 mg/L at 48 hours (WAF)
NOEL	355.6 mg/L at 48 hours (WAF)
Remarks - Results	All validity criteria for the test were satisfied. It was observed in a middle treatment, which is 632.4 mg/L, that the 50% immobility of the test organisms was achieved. However, this is inconsistent with the mortality achieved from other treatments. There was no evidence of a dose response in this study. Therefore, the 50% mortality observed at the

treatment, which is 632.4 mg/L, is regarded as an outlier.

CONCLUSION	The notified polymer is not harmful to aquatic invertebrates
TEST FACILITY	STL (2002b)

A.2.3. Toxicity to marine benthic organisms

TEST SUBSTANCE	Notified polymer
METHOD	A Sediment Bioassay using An Amphipod *Corophium* sp. Oslo and Paris Commission (PARCOM) Method (1995)
Species	Sediment Re-Worker (*Corophium volutator*)
Exposure Period	10 day
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. A control and five treatment concentrations for the test substance were prepared. Predetermined amounts of the test substance were added to the test vessels containing the wet sediment and mixed thoroughly. 100 mL of seawater was then added to each vessel. Untreated controls were prepared in a similar way without the addition of test material.

RESULTS

Nominal Concentration (mg/kg)	*Number of C. volutator*	*Number Immobilised*
0	100	8
1,000.0	60	12
1,778.3	60	3
3,162.3	60	13
5,623.4	60	7
1,0000.0	60	13

LC50	>10,000 mg/kg at 10 days
NOEC	≥10,000 mg/kg at 10 days
Remarks - Results	All validity criteria for the test were satisfied. There was no evidence of a dose response in this study. Therefore, the LC50 is considered to be > 10,000 mg/kg, the top tested level. The notified polymer is considered to be very slightly toxic according to the acute toxicity classification for earthworms in Mensink et al. (1995). It is considered to be equivalent to 'not harmful' although the toxicity classification for sediment worker is not provided in the GHS.
CONCLUSION	The notified polymer is not harmful to sediment re-Worker.
TEST FACILITY	STL (2002c)

A.2.4. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	ISO/DIS10253, detailed in STL Runcorn SOP III.19.
Species	Marine Alga (*Skeletonema costatum*)
Exposure Period	72 hours
Concentration Range	Nominal: 100.0, 177.8, 316.2, 562.3, 1000.0 mg/L
Auxiliary Solvent	Not reported

Water Hardness	Not reported
Analytical Monitoring	Not reported
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The above test guideline is similar to the OECD TG 201 Alga, Growth Inhibition Test. Water Accommodated Fractions (WAFs) containing the test substance for all treatment concentrations were prepared. The mixture was mixed overnight and following a 4 hour settling period, supernatant was removed and used as treatment solution.

RESULTS

Growth	
E_rL50 (mg/L)	*NOE_rL (mg/L)*
619.02	*562.3*

Remarks - Results	All validity criteria for the test were satisfied. It was noted that the growth inhibition for the reference toxicant test using DCP (3,5-dichlorophenol) did not fall between the acceptable inhibition rate of 20–80% after 72 hours exposure. The study outcome is considered reliable as effects on alga were observed and the EC50s were calculable, and the control growth was acceptable.

CONCLUSION The notified polymer is not harmful to algae

TEST FACILITY STL (2002d)

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