File No: LTD/1823

September 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in CFR-8L

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
LTD/1823	BASF Australia Ltd Halliburton Australia Pty Ltd	Polymer in CFR-8L	ND*	≤ 10 tonne/s per annum	Additive in cement

*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 of 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 reported use pattern and limited aquatic exposure, 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 the notified polymer:
  - Avoid contact with skin and eyes

- 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:
  - Coveralls, impervious gloves, 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 of 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.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical 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 1000;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from additive in cement, 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 provided by the notifier was 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)
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

Halliburton Australia Pty Ltd (ABN: 73 009 000 775)
Level 17, 444 Queen Street
BRISBANE QLD 4000

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, 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 except partition co-efficient and particle size.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada, Europe, Switzerland, Taiwan and USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CFR-8L (product containing the notified polymer at 30-60% concentration)

MOLECULAR WEIGHT
> 1,000 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Powder orange or brown in colour

Property	Value	Data Source/Justification
Melting Point	> 270 °C	(M)SDS - Decomposes prior to melting
Boiling Point	> 270 °C	(M)SDS - Decomposes prior to boiling
Density	350 - 450 kg/m^3	(M)SDS – Bulk density of the powder
Vapour Pressure	Not determined	expected to be low due to the high molecular weight

Water Solubility	> 400 g/L at 20 °C	(M)SDS
Hydrolysis as a Function of pH	Not determined	Contains amide bonds that may hydrolyse under extreme conditions
Partition Coefficient (n-octanol/water)	log Pow < 0 at 20 °C	Estimated as a ratio between solubility in n-octanol and solubility in water due to low n-octanol solubility
Adsorption/Desorption	Not determined	Not expected to adsorb to soil and sediment based on high water solubility and low partition coefficient
Dissociation Constant	Not determined	Potential to ionise under environmental pH (4-9)
Particle Size	Inhalable fraction (< 100 μm): 75.43% Respirable fraction (< 10 μm): 7.86%	Measured (study report not sighted)
Flash Point	Not determined	Imported in solution
Autoignition Temperature	Not determined	Not expected to autoignite prior to decomposition
Explosive Properties	Lower explosion limit: 60 g/m^3 Minimum ignition energy 10 J (dust)	(M)SDS
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 of 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 and/or reformulated in Australia. The notified polymer will be imported into Australia in end-use products at ≤ 60% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes BASF	≤ 5	≤ 5	≤ 5	≤ 5	≤ 5
Tonnes Halliburton	≤ 10	≤ 10	≤ 10	≤ 10	≤ 10

PORT OF ENTRY
Adelaide, Fremantle, Brisbane and Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported into Australia in 20 L buckets secured on pallets, or in 1,000 L intermediate bulk containers. The products containing the notified polymer will be transported by road and/or sea to the site of use.

USE
The notified polymer will be used as dispersant in well cementing and side tracking operations. This will involve the placement of cement slurry into the space between the casing and borehole wall of the well. The notified polymer will act as a dispersant to lower the slurry's viscosity in order to enhance slurry flow and increase completion efficiency and aid side tracking.

OPERATION DESCRIPTION
The imported product CFR-8L (< 60% notified polymer) will be pumped from the imported containers to the mixing tank or added directly to the mixing tank where it will be combined with the other cement components. Once the cement slurry has formed it will be pumped down the well between the casing and the borehole wall where the slurry will harden trapping the notified polymer within it. Approximately 95% of the notified polymer will remain permanently in the down-hole in the hardened cement. The remaining will be contained on-site within excess cement and the notifier has stated it will be disposed of in accordance with all local regulations. During side tracking operations, some of the hardened cement may be drilled out and cuttings returned to the surface with the notifier stating that it will be disposed of in accordance with all local regulations.

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)*
Cementing engineer	≤ 3	12
Cementing supervisor	≤ 3	12
Drilling mud engineer	2-4	12

EXPOSURE DETAILS
Storage and transport workers are not expected to be exposed to the notified polymer except in the unlikely event of an accidental release due to a container breach or spill.

Drilling and cementing workers may experience dermal and ocular exposure to the product containing the notified polymer (at ≤ 60% concentration) during addition of it to the mixing tank, sampling for quality control and equipment cleaning and maintenance. Operations involving the transfer of the product into wells will be performed using closed systems in well ventilated areas. The notifier has stated that the workers are expected to wear personal protective equipment (PPE), such as gloves, eye protection and coveralls to minimise exposure. In addition, the pumping operations involving the notified polymer will be of short duration and of relatively low frequency, further minimising the potential for exposure.

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
The results from a toxicological investigation conducted on the notified polymer is summarised below. For full details of the study, refer to Appendix B.

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 high molecular weight (> 1,000 Da.) and the expected low partition coefficient (log Pow < 0), bioavailability of the notified polymer is expected to be low.

Acute toxicity
The notified polymer was found to be of low toxicity in rats with the LD_{50} > 2,000 mg/kg body weight.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of 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

The notified polymer is not expected to be hazardous to human health. Dermal and potentially ocular exposure to the notified polymer (at ≤ 60% concentration) may occur during addition of it to the mixing tank, sampling for quality control and equipment cleaning and maintenance. The expected use of enclosed and automated process and the use of PPE such as impervious gloves, safety glasses and coveralls as anticipated by the notifier in the application dossier should minimize the potential for exposure.

Therefore, considering the expected low hazard and the low exposure to the notified polymer, including the use of PPE, 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 notified polymer is intended only for industrial use. Therefore, the risk to the public from use of the notified polymer at ≤ 60% concentration 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 dispersant and side tracking aid for cement slurries in down-hole cementing operations 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 by physical containment, and disposed of by licensed waste management services in accordance with local government regulations, most likely to landfill.

RELEASE OF CHEMICAL FROM USE

The product containing the notified polymer will be used in cementing processes in off-shore (> 90%) and on-shore (< 10%) well drilling and well formation operations. The product containing the notified polymer will be mixed into the cement slurry, then pumped directly into the annuli of drilling wells to secure cement casings. Once cured, the notified polymer will be irreversibly bound to the cement matrix and share the fate of the cement. It is estimated by the notifier that 95% of the notified polymer will subsequently remain down-hole bound within the cement matrix; the remainder in excess cement slurry at the well surface will be drilled out once cured, and cuttings collected for disposal in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

As the notified polymer will be used in cement slurries 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. Any import container residue, spills, or waste generated from cementing operations of the product containing the notified polymer will be collected and disposed of in accordance with local government regulations.

7.1.2. Environmental Fate

The notified chemical is not readily biodegradable; however, it is expected to eventually degrade in the environment (19-38% in 28 days in seawater). For details of the environmental fate studies, please refer to Appendix C.

Under most circumstances, the majority of the notified polymer will be incorporated into cement slurries and once cured, be irreversibly bound into the cement matrix and share the fate of the cement. Although the notified polymer has high water solubility and is not considered to be readily biodegradable, based on its high molecular weight, low partition coefficient (log P_{OW} < 0), and limited expected release to the aquatic environment, the notified polymer is not expected to be bioaccumulative or bioavailable. Notified polymer disposed of to landfill

as waste is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, nitrogen and sulphur.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated, since no significant release of the notified polymer to the aquatic environment is expected from the reported use pattern.

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 LC50 > 1,006 mg/L	Not harmful to marine fish
Marine Invertebrate Toxicity	48 h EC50 = 2,200 mg/L	Not harmful to marine copepods
Marine Algal Toxicity	72 h E_rC50 = 2,480 mg/L	Not harmful to marine algae
Marine Sediment Re-worker Toxicity	10 d LC50 = 1,367 mg/kg (dry wt)	Not harmful to marine sediment re-worker

Based on the above ecotoxicological endpoints for the notified polymer, it is not considered to be harmful to marine fish, marine invertebrates, marine algae, and marine sediment re-workers. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) (United Nations, 2009), the notified polymer is not formally classified for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for marine fish (LC50 > 1006 mg/L). A safety factor of 100 was used given endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, 96 h)	> 1,006	mg/L
Assessment Factor	100	
Mitigation Factor	1.00	
PNEC:	> 10,060	µg/L

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) of the notified polymer has not been calculated, since the PEC was not calculated, and due to its low potential for release to the aquatic compartment. When used as a cementing dispersant and side tracking agent, the notified polymer will be irreversibly bound within the inert cement matrix, and is not likely to be released into the aquatic environment in a bioavailable form. Whilst the notified polymer is not readily biodegradable, it is considered inherently biodegradable, and is expected to have a low potential for bioaccumulation based on its high molecular weight and low log P_{OW}.

On the basis of its limited aquatic exposure, low toxicity to aquatic organisms, and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Partition Coefficient (n-octanol/water) log Pow < 0 at 20 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	Estimated as a ratio between solubility in n-octanol and solubility in water due to low n-octanol solubility.
Test Facility	M-Lab (2003e)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Crl:CD(SD)IGS BR
Vehicle	Deionized water
Remarks - Method	No significant protocol deviations. The animals were observed for 14days after exposure and were sacrificed on day 14 for post mortem studies.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 female	2,000	0/3
2	3 female	2,000	0/3

LD50	> 2,000 mg/kg bw
Signs of Toxicity	There were no deaths or test substance-related clinical signs
Effects in Organs	There were no remarkable necropsy findings.
Remarks - Results	Body weight and weight gains were not affected.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	ARC (2005)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 306 Biodegradability in Seawater: Closed Bottle Test. OSPARCOM/SFT 2000.
Inoculum	Natural seawater from an unpolluted site in Byfjord, Norway, at a depth of 80 m.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Oxygen Demand (ThOD)
Remarks - Method	No significant deviation in protocol.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	19	7	82
14	25	14	86
21	33	21	91
28	38	28	94

Remarks - Results	The temperature of the test conditions was 20.5-23.4 °C, which was outside the range reported in the study (20 ± 2 °C); however, this was not deemed to have had a significant impact on the validity or the integrity of the study. All other validity criteria for the test were met and satisfied. The percentage degradation of the reference compound, sodium benzoate, surpassed the threshold level of 70% by 7 days (82%), and reached 94% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The notified polymer attained 38% degradation by 28 days. Therefore, the test substance cannot be classified as readily biodegradable.
CONCLUSION	The test substance is not readily biodegradable in seawater.
TEST FACILITY	RF-Miljolab (2002)

C.1.2. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 306 Biodegradability in Seawater: Closed Bottle Test. OSPARCOM/SFT 2000.
Inoculum	Natural seawater from an unpolluted site in Byfjord, Norway, at a depth of 80 m.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Oxygen Demand (ThOD)
Remarks - Method	No significant deviation in protocol.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	22	7	82
14	25	14	88
21	27	21	91
28	29	28	95

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate, surpassed the threshold value of 70% by 7 days (82%), and reached 95% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The test substance attained 29% degradation by 28 days. Therefore the test substance cannot be classified as readily biodegradable.
CONCLUSION	The test substance is not readily biodegradable in seawater.
TEST FACILITY	M-Lab (2003f)

C.1.3. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	Marine BODIS – ISO/TC 147/SC 5/WG 4N 141.
Inoculum	Raw seawater from Sutherland's pier on the west side of Flotta in Scapa Flow, UK, at a depth of 2 m below spring tide level.
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical Oxygen Demand (BOD)
Remarks – Method	No significant deviation in protocol.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	5	7	63
14	9	14	71
21	12	21	76
28	19	28	84

Remarks – Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate, surpassed the threshold value of 60% by 7 days (63%), and reached 84% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The test substance attained 19% degradation by 28 days. Therefore the test substance cannot be classified as readily biodegradable.
CONCLUSION	The test substance is not readily biodegradable in seawater.
TEST FACILITY	Opus (2007)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	PARCOM Protocols on Methods for the Testing of Chemicals Used in the Offshore Industry – Part B: Protocol for a Fish Acute Toxicity Test – Semi-static.
Species	*Scophthalmus maximus*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Salinity	33 ± 2‰
Analytical Monitoring	No analytical verification of the test substance concentrations.
Remarks – Method	No significant deviation in protocol.

RESULTS

Nominal Concentration mg/L	*Number of Fish*	*Mortality*			
		24 h	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0
100	10	0	0	0	0
182	10	0	0	0	0
327	10	0	0	0	0
561	10	0	0	0	0
1006	10	0	0	0	0

LC50	> 1,006 mg/L at 96 hours.
NOEC	1,006 mg/L at 96 hours.
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were renewed after 48 hours during the test period. The 96 h LC50 and NOEC for fish were determined to be > 1,006 mg/L and 1,006 mg/L, respectively, based on the nominal loading concentration.
CONCLUSION	Under the conditions of the study, the test substance is not considered to be harmful to marine fish.
TEST FACILITY	M-Lab (2003d)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	ISO 14669 – 1999: Water Quality – Determination of Acute Lethal Toxicity to Marine Copepods (Copepoda, Crustacea).
Species	*Acartia tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Salinity	34.2‰
Analytical Monitoring	No analytical verification of the test substance concentrations.
Remarks - Method	No significant deviation in protocol.

RESULTS

Nominal Concentration mg/L	*Number of A. tonsa*	*Cumulative Mortality (%)*	
		24 h	*48 h*
Control	29	0	3.4
99.2	20	0	0
179	20	5	10
320	20	15	25
560	20	20	25
1002	21	19	28.6
1802	22	22.7	45.5
3201	19	84.2	100

LC50	2,200 mg/L at 48 hours
NOEC (or LOEC)	560 mg/L at 48 hours
Remarks - Results	The dissolved oxygen concentration in the highest test concentration was 0.7 mg/L at 48 hours, which falls significantly outside of the acceptance criteria stated in the study (> 4 mg/L). All other validity criteria for the test were met and satisfied. The 48 h LC50 and NOEC for copepods were determined to be 2,200 mg/L and 560 mg/L, respectively, based on the nominal loading concentration. However, the NOEC was not calculated according to the study protocol (determination method not stated), and cannot be verified.
CONCLUSION	Under the conditions of the study, the test substance is not considered to be harmful to marine copepods.
TEST FACILITY	M-Lab (2003b)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	NS-EN ISO 10253, 1998: Water Quality – Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum* – Static.
Species	*Skeletonema costatum*
Exposure Period	72 hours
Concentration Range	Nominal: 100-3,200 mg/L
Auxiliary Solvent	None
Water Salinity	34.2‰
Analytical Monitoring	No analytical verification of the test substance concentrations.
Remarks - Method	No significant deviation in protocol.

RESULTS

Biomass		*Growth*	
E_bC50 mg/L at 72 h	*NOE_bC mg/L*	*E_rC50 mg/L at 72 h*	*NOE_rC mg/L*
Not determined	Not determined	2480 (95% CL 2,292-2,709 mg/L)	320

Remarks - Results	All validity criteria for the test were satisfied. The 72 h E_rC50 and NOE_rC were determined to be 2,480 mg/L (95% CL 2,292-2,709 mg/L) and 320 mg/L, respectively, based on the nominal loading concentration.
CONCLUSION	Under the conditions of the study, the test substance is not considered to be harmful to marine algae.
TEST FACILITY	M-Lab (2003a)

C.2.4. Sediment re-worker toxicity test

TEST SUBSTANCE	Notified polymer
METHOD	PARCOM Protocols on Methods for the Testing of Chemicals Used in the Offshore Industry – Part A: A sediment Bioassay Using an Amphipod *Corophium* sp.
Species	*Corophium volutator*
Exposure Period	10 days
Concentration Range	Nominal: 134-1,524 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 and exposed for a period of 10 days in a static test at 15 ± 2 °C. Three replicates were prepared for the test concentration and six 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	3.3
134	6.7
305	6.7
675	33.3
1,524	53.3

LC50	1,367 mg/kg (dry wt) at 10 days
NOEC	305 mg/kg (dry wt) at 10 days
Remarks – Results	The temperature of the testing facility reached a maximum of 18 °C, which

	falls outside the acceptance criteria stated in the study (15 ± 2 °C); however, this was not deemed to have had a significant impact on the validity or the integrity of the study. All other validity criteria for the test were met and satisfied. The 10 d LC50 and NOEC were determined to be 1,367 mg/kg (dry weight of sediment) and 305 mg/kg (dry weight of sediment), respectively, based on the nominal loading concentration.
CONCLUSION	Under the conditions of the study, the test substance is not considered to be harmful to the sediment re-worker.
TEST FACILITY	M-Lab (2003c)

BIBLIOGRAPHY

ARC (2005) [Notified polymer] Acute Oral Toxicity study with Rats (Acute Toxic Class Method (Study No. SKW282, May, 2005). Seibersdorf, Austria, ARC Seibersdorf Research GmbH (unpublished report submitted by the notifier).

M-Lab (2003a) [Notified polymer] Toxicity Test with the Marine Algae *Skeletonema costatum* (Study No. 03/11086-1, August 2003). Stavanger, Norway, M-Lab (Unpublished report submitted by the notifier).

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