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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

MK216K

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.

This Public Report is 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/1568	Baker Hughes Australia Pty Ltd	MK216K	Yes	< 150 tonnes per annum	A component of a corrosion inhibitor in the oil and gas industry

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited available information, 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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

However, the notifier has listed the polymer as a skin and eye irritant equivalent to the following classifications according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

Hazard classification	*Hazard statement*
Skin irritant (category 2)	H315 – Causes skin irritation
Eye irritant (category 2A)	H319 – Causes serious eye irritation

Or according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R36/38: Irritating to eyes and skin

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 1)	H400 - Very toxic to aquatic life

Human health risk assessment
Provided that the recommended controls are being adhered to, 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 and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - H315 – Causes skin irritation
  - H319 – Causes serious eye irritation

The above should be used for products/mixtures containing the notified polymer, if applicable, based on the concentration of the notified polymer present and the intended use/exposure scenario.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer the notified polymer as introduced and in the formulated product:
  - Possible use of the local exhaust ventilation

- 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 as introduced and in the formulated product:
  - 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 as introduced and in the formulated product:
  - Gloves
  - Goggles
  - Protective clothing
  - Respiratory protection when ventilation is not adequate

  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 chemical/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 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(2) of the Act; if
- the function or use of the polymer has changed from a component of a corrosion inhibitor in the oil and gas industry, 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)SDSs of the notified polymer and product containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDSs remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Baker Hughes Australia Pty Ltd (ABN: 20 004 752 050)
5 Walker Street
BRAESIDE VIC 3195

NOTIFICATION CATEGORY
Standard: Synthetic polymer with Mn < 1,000 Da (more than 1 tonne per year).

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point/Freezing Point, Boiling Point Density, Vapour Pressure, Hydrolysis as a Function of pH, Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability, Autoignition Temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Commercial evaluation chemical (CEC) permit (2013)

NOTIFICATION IN OTHER COUNTRIES
Canada (1997)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
MK216K

MOLECULAR WEIGHT
< 500 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 99%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

DEGRADATION PRODUCTS
Degradation products are expected to be oxides of nitrogen and carbon.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: viscous brown liquid

Property	Value	Data Source/Justification
Pour Point	-23 °C	(M)SDS*
Boiling Point	> 200 °C	Measured (ASTM D86)
Density	1,033 kg/m^3 at 16 °C	(M)SDS
Vapour Pressure	< 0.7 kPa at 38.7 °C	Measured (ASTM D5191)
Water Solubility	> 1 g/L at 20 - 25°C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality and is expected to be hydrolysed under normal environmental conditions (pH 4 – 9).
Partition Coefficient (n-octanol/water)	log Pow = 1.05 to 4.47	Measured. Expected to partition to the interface between octanol and water, based on its surfactant properties.
Adsorption/Desorption	Not determined	The notified polymer has potential to adsorb to sediment and any suspended particulate matter, based on its potential cationic and surfactant properties.
Dissociation Constant	Not determined	Contains ionisable functionalities. Therefore, the notified polymer is expected to be ionised under normal environmental conditions of pH 4 to 9.
Flash Point	> 65 °C (closed cup)	(M)SDS
Autoignition Temperature	> 200 °C	Measured
Explosive Properties	Not determined	Contains no explosophores that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

*Product containing the notified polymer at a concentration of 60-100%.

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 be imported products at concentrations of 60-100% for further reformulation in Australia, or it will imported in end use products at ≤ 30% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 100	< 100	< 150	< 150	< 150

PORT OF ENTRY
Melbourne and Fremantle

TRANSPORTATION AND PACKAGING
The notified polymer will be imported into Australia in sealed 205 L plastic or plastic-lined steel drums or in intermediate bulk containers (IBCs) and will be transported by road.

After reformulation, products containing the notified polymer will be transferred into 1,350 L or larger stainless steel IBCs and transported via road to port from where they are shipped to a number of potential end users.

USE
The notified polymer will be used as a component (5-30% concentration) of a corrosion inhibitor in the oil and gas industry, for onshore (5%) and offshore (95%) applications.

OPERATION DESCRIPTION
The notified polymer will not be manufactured within Australia.

Reformulation
During reformulation, the notified polymer at up to 100% concentration will be pumped from the imported containers into a mixing tank. The containers will be connected to the mixing tank by tubes/hoses using a cam lock coupling, quick-connection. Following blending, the same tubes, pump and hoses will be used to transfer the formulated product containing the notified polymer at up to 30% concentration to intermediate bulk containers (IBCs) or bulk transport tanks to be sent to end users.

End-use
The containers or drums of the notified polymer formulation will be injected into the production system at rates of several ppm to several tens of ppm.

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)*
Blend plant workers	2-3	10-20
Transportation workers	1	5-10
Oil field technician	1	10-20

EXPOSURE DETAILS
Transport and storage workers
Transport and storage workers will only come into contact with the notified chemicals (up to 100% concentration) in the unlikely event of an accident.

Reformulation
Dermal and ocular exposure to the notified polymer at up to 100% concentration is possible when plant operators are connecting and disconnecting pump lines to storage tanks or blending vessels. Dermal exposure is also possible when cleaning up spills or leaks and during maintenance of the blend vessel. Workers involved in the blending process are expected to wear gloves, goggles and protective clothing to minimise exposure.

Inhalation exposure is expected to be low given the low vapour pressure of the notified polymer (< 0.7 kPa at 38.7 °C). In addition, potential for inhalation exposure will be minimised by the use of local exhaust ventilation.

End use
There is potential for dermal and ocular exposure to the notified chemical at up to 30% concentration during the connection and disconnection of the chemical injection pump facility to the tank containing the reformulated scale inhibitor. Exposure is expected to be minimised by the use of gloves, goggles and protective clothing.

6.1.2. Public Exposure
The notified polymer will only be used by the oil and gas industry and public exposure is not expected.

6.2. Human Health Effects Assessment

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

Endpoint	*Result and Assessment Conclusion*

Rat, acute dermal toxicity	LD50 > 2,000 mg/kg bw;low toxicity
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution
No information on the toxicokinetics of the notified polymer was provided. For dermal absorption, molecular weights below 100 Da are favourable for absorption and molecular weights above 500 Da do not favour absorption (ECHA, 2014). Dermal uptake is likely to be moderate to high if the water solubility is between 100-10,000 mg/L, with Log P values between 1 and 4 also favouring dermal absorption (ECHA, 2014). Based on the water solubility (> 1 g/L), partition coefficient (log Pow = 1.05 to 4.47) and moderate molecular weight (between 100 and 500 Da) of the notified polymer, dermal absorption may occur. Given its low vapour pressure, exposure by inhalation is not expected, unless aerosols/mists are formed.

Acute toxicity
Based on studies conducted in rats on the notified polymer, the notified polymer was considered to have low acute dermal toxicity.

Irritation and sensitisation
In an acute dermal toxicity study on the notified polymer slight to well-defined erythema was observed. The (M)SDS for the notified polymer reported that it may cause eye and skin irritation; prolonged, repeated or high inhalation exposures may cause irritation to the respiratory tract (nose, mouse, mucous membranes). This is consistent with a structural alert for corrosion/irritation present in the notified polymer.

No information on the sensitisation potential of the notified polymer was provided.

Repeated dose toxicity
No information was provided.

Mutagenicity/Genotoxicity
The notified polymer was not considered to be mutagenic in a bacterial reverse mutation study.

Health hazard classification
Based on the limited available information, 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, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

However, the notifier has listed the polymer as a skin and eye irritant equivalent to the following classifications according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

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R36/38: Irritating to eyes and skin

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer is expected to be a skin and eye irritant, and its chronic toxicity and sensitising effects are unknown.

Workers are at greatest risk of exposure while handling the imported notified polymer at up to 100% concentration during reformulation and at up to 30% concentration during the connection and disconnection of the chemical injection pump facility. The use of PPE such as gloves, goggles and protective clothing, as well as automated processes, is expected to minimise dermal and ocular exposure and therefore the risk of skin or eye

irritation. Although the sensitisation and chronic toxicity effects of the notified polymer are unknown the expected low exposure should reduce the potential for these effects as well.

Provided that control measures stated by the notifier are in place, 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 and the finished products containing it are intended for industrial applications only, hence public exposure is not expected. Therefore, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as components of a corrosion inhibitor in the oil and gas industry, for onshore (5%) and offshore (95%) applications. The notified polymer expected to be reformulated in automated enclosed systems. Therefore, significant environmental releases are not expected from reformulation in Australia. Accidental spills during transport are expected to be handled by physical containment, collection and subsequent safe disposal.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used as corrosion inhibitor in oil/gas wells. The notified polymer in formulated products will be injected into the produced water and this may be injected downhole into a disposal reservoir. The majority of the notified polymer will then flow back with the produced fluids to the processing facilities. Notified polymer contained in the produced water is expected to be either reinjected into wells or further treated before disposed of as waste water.

For onshore applications, significant release of the notified polymer to the aquatic environment is not expected. The notifier indicates that the produced water containing the notified polymer will be treated via an on-site evaporation pond before discharging to sewers for further treatment. Therefore, the notified polymer is not expected to be released significantly to surface waters from onshore applications.

Notified polymer within the oil phase will either share the same end-use fate as the oil or be removed during oil refining, in which case it will remain in the distillation residues/tar fraction. Environmental release of the notified polymer in oil pipelines is expected to be limited.

RELEASE OF CHEMICAL FROM DISPOSAL

Spillage of small amounts of the notified polymer is expected to be soaked up with absorbent material which is expected to be disposed of to landfill. The empty 200 L import containers are expected to be recycled or disposed of to landfill.

7.1.2. Environmental Fate

Off shore fate

A ready biodegradation test for the notified polymer indicates that it is readily biodegradable in the marine environment (70% over 28 days). For the details of the environmental fate study, please refer to Appendix C. For offshore application in oil production, the notified polymer in produced water is expected to be released into ocean after use. In the marine environment, the notified polymer has potential to adsorb to sediment and any suspended particulate matter, based on its potential cationic and surfactant properties. Based on these properties, the notified polymer is not expected to be bioaccumulative in aquatic organisms. Due to its ready biodegradability, the notified polymer is not expected to be significantly bioavailable in the receiving marine environment. In sea water, the notified polymer is expected to degrade via abiotic or biotic pathways forming water and oxides of carbon, and nitrogen.

On shore fate

It is estimated by the notifier that only 5% of the notified polymer in formulated products will be used in onshore application. The notified polymer in the produced water is expected to be treated onsite as it is expected to be sent to an evaporation pond. The notified polymer in the produced water is expected to be efficiently removed by adsorbing to sludge sediment. The treated produced water is expected to be further treated at STPs before being released as treated effluent to the aquatic environment. At STPs, the notified polymer is expected to be removed from the water column by adsorbing to sludge based on its surfactant properties. The notified polymer that partitioned to sludge are expected to be disposed to landfill or used for soil remediation. Therefore, very little, if any, of the notified polymer is expected to be released to surface waters from onshore applications. In water, landfill and soil, the notified polymer is expected to degrade via abiotic or biotic pathways forming water and oxides of carbon, and nitrogen.

Small amounts of the notified polymer contained in the oil phase are expected to be sent to oil refineries. They may either be removed during oil refining and remain in the distillation residues/tar fraction that will be most likely used as road base, or share the fate of the oil product. The oil products are expected to be eventually thermally decomposed during use to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Offshore release

The calculations of the predicted environmental concentrations (PECs) of the notified polymer in sea water from offshore applications has been calculated based on CHARM modelling (Thatcher et al, 2005). For the key parameter, the concentration of the notified polymer in the produced water from oil production was reported by the notifier to be 2 mg/L. For a worst case scenario, it is assumed that all the produced water will be directly discharged into the ocean. The worst case PEC was determined to be 2 µg/L on the assumption of 1000 fold dilution by the sea water after the discharge of the water based on the CHARM model. For details of the calculation, please refer to Appendix D.

Onshore release

The notified polymer in produced water is expected to be treated onsite before it is released to STPs. The notified polymer in produced water is expected to be efficiently removed by adsorbing to sludge sediment and/or biodegradation at the onsite treatment system. The treated produced water is expected to be further treated at STPs. Therefore, the release of the notified polymer to aquatic environment from onshore application is not expected to reach ecotoxicologically significant concentrations. Hence, the PEC for the notified polymer released from the onshore applications 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 C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 = 21 mg/L	Harmful to fish
Aquatic Invertebrates	48 h EC50 = 2.9 mg/L	Toxic to aquatic invertebrates
Algal Toxicity	72 h E_rC50 = 0.22 mg/L	Very toxic to marine algae
Amphipods	10 d LC50 = 1158 mg/kg dry weight	Very slightly toxic to sediment re-Worker

Under the Globally Harmonised System of Classification and Labelling of Polymer (GHS; United Nations, 2009) the notified polymer is considered to be harmful to fish, toxic to aquatic invertebrates, but is considered to be very toxic to algae. Based on the toxicity to algae the notified polymer is formally classified under the GHS as "Acute category 1; Very toxic to aquatic life". The notified polymer is demonstrated to be readily biodegradable. Therefore, the notified polymer has not been formally classified for long term hazard 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 = 0.22 mg/L) and an assessment factor of 100 as endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment	
EC50 (Alga).	0.22 mg/L
Assessment Factor	100
PNEC:	2.2 µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) for the offshore application has been calculated using the PEC value of 2.0 µg/L (refer to the Appendix D for PEC calculation).

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - Ocean	2	2.2	0.909

The risk quotient (RQ = PEC/PNEC) for this release scenario is < 1. However, the RQ value is very close to 1. It is noted that this calculation is based on the conservative assumption that the total amount of the notified polymer used for an off-shore application for oil production is disposed of to the ocean. No removal to the sediment or via biodegradation has been considered. Therefore, the actual Q value is expected to be lower. The Risk Quotient for on-shore use was not calculated given the PEC has not been calculated due to the expected low release to aquatic environment.

Based on its high water solubility and surfactant property, the notified polymer is not expected to bioaccumulate in aquatic organisms. The notified polymer is readily biodegradable, thus it is not expected to be significantly bioavailable in receiving water. Therefore, on the basis of the marine PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment for both offshore and onshore oil and gas applications.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility > 1g/L at 20 °C

Method	OECD TG 105 Water Solubility. EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks	Flask Method
Test Facility	Analytical Services (1997a)

Partition Coefficient (n-octanol/water) log Pow = -1.11 - 4.50

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	HPLC Method
Test Facility	Analytical Services (1997b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Sprague-Dawley CD (crl:CD®BR)
Vehicle	None
Type of dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	2,000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity - Local	Slightly light brown-coloured staining, caused by the test substance, was noted during the study. Signs of skin irritation were very slight to well-defined erythema.
Signs of Toxicity - Systemic	No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necropsy.
Remarks - Results	All animals showed expected gain in bodyweight during the study.
CONCLUSION	The notified polymer is of low toxicity via the dermal route.
TEST FACILITY	Safepharm (1997a)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA$^-$
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver
Concentration Range in Main Test	a) With metabolic activation: 0, 5, 15, 50, 150, 500, 1,500, 5,000 µg/plate b) Without metabolic activation: 0, 0.5 (only used in test 2), 1.5, 5, 15, 50, 150, 500, 1,500, 5,000 µg/plate
Vehicle	Water
Remarks - Method	No significant protocol deviations

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	≥ 150			
Test 1		≥ 150	> 5,000	negative
Test 2		≥ 150	> 5,000	negative
Present				
Test 1		≥ 500	> 5,000	negative
Test 2		≥ 500	> 5,000	negative

Remarks - Results	No significant increase in the frequency of revertant colonies was recorded for any of the bacterial strains with any dose of the test substance either with or without metabolic activation.

	The positive controls produced satisfactory responses, thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.
CONCLUSION	The notified polymer was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Safepharm (1997b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.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 acetate (reference substance)*	
Day	*% Degradation (2 mg/L)*	*Day*	*% Degradation*
5	24	5	93
13	43	13	100
20	58	20	100
28	70	28	100

Remarks - Results	All validity criteria for the test were satisfied. The reference compound reached the 60% pass level by day 5 indicating the suitability of the inoculum. The toxicity control was not included in the study. The percent degradation of the notified polymer reached 43% at the end of the 10-day window. According to the nature of the test substance, 10-day window is not applicable as stated in OECD Guidelines for Testing Chemicals, Section 3. However, a criterion, which states that the test substance should degrade biotically in the environment by > 60% in 28 days, is required to be demonstrated to meet the rapid biodegradation criteria according to the GHS (GHS; United Nations, 2009). Therefore, the test substance can be classified as readily biodegradable according to the OECD 306 guideline.
CONCLUSION	The notified polymer is readily biodegradable.
TEST FACILITY	AnalyCen (1997)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified polymer
METHOD	Acute Toxicity Test: OECD TG 203 - Semi-Static
Species	Juvenile Turbot (*Scophthalmus maximus*)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Salinity	Seawater
Analytical Monitoring	None reported
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP). No significant deviations from the test guidelines were reported.

RESULTS

Nominal Concentration (mg/L)	*Number of Fish*	*Mortality(96 h)*			
		24h	*48h*	*72h*	*96h*
Control	7	0	0	0	0
1.0	7	0	0	0	0
3.2	7	0	0	0	0
10	7	0	0	0	0
32	7	100	100	100	100
100	7	100	100	100	100

LC50	21 mg/L at 96 hours
NOEC	10 mg/L at 96 hours
Remarks – Results	All validity criteria for the test were satisfied. The test solutions were renewed at 48 hours. Nominal treatment concentrations were used. End points were calculated based on the proportional response data using ToxCal V5.

CONCLUSION The notified polymer is harmful to marine fish.

TEST FACILITY AnalyCen (2003)

C.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). No significant deviations from the test guidelines were reported. The above stated test guideline is very similar to OECD TG 202.

RESULTS

Nominal Concentration (mg/L)	*Number of A.tonsa*	*Cumulative % Immobilised 48 h*
Control	20	0
0.1	20	0
0.5	20	0
2.5	20	15
10	20	100

EC50	2.9 mg/L at 48 hours
NOEC	0.5 mg/L at 48 hours
Remarks - Results	All validity criteria for the test were satisfied. Nominal treatment concentrations were used in the study. The EC50 value was calculated based on a Logistic Regression Model using JMP Program.

CONCLUSION The notified polymer is toxic to marine aquatic invertebrates

TEST FACILITY AnalyCen (2003)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified polymer
METHOD	ISO/DIS10253.2, detailed in STL Runcorn SOP III.19.
Species	Marine Alga (*Skeletonema costatum*)
Exposure Period	72 hours
Concentration Range	Nominal: 0.01, 0.02, 0.04, 0.08, 0.15, 0.28, 0.53, 1.0, 1.9, and 3.6 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). No significant deviations from the test guidelines were reported. The above test guideline is similar to the OECD TG 201 Alga, Growth Inhibition Test.

RESULTS

Biomass (72 h)		*Growth (72 h)*	
E_yC50 (mg/L)	*NOEC (mg/L)*	*E_rC50 (mg/L)*	*NOEC (mg/L)*
0.18	0.01	0.22	0.15

Remarks - Results	All validity criteria for the test were satisfied. 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 very toxic to marine algae.
TEST FACILITY	Baker (2013)

C.2.4. Toxicity to marine benthic organisms

TEST SUBSTANCE	Notified polymer
METHOD	A Sediment Bioassay using An Amphipod *Corophium* sp. Oslo and Paris Commission (PARCOM) Method (1994)
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.

RESULTS

Nominal Concentration (mg/kg; dry weight)	*Number of C. volutator*	*Number of mortalities*
Control	50	0
52	30	0
251	30	0
877	30	12
3000	30	26
1007	30	30

LC50	1158 (881 – 1533) mg/kg (dry weight) at 10 days
NOEC	251 mg/kg (dry weight) at 10 days
Remarks - Results	All validity criteria for the test were satisfied. The endpoints were calculated based on the dry weight of the sediment used.

CONCLUSION	The notified polymer is very slightly toxic to marine sediment re-Worker.
TEST FACILITY	AnalyCen (2004)

APPENDIX D

Assuming for the worst case scenario that all the produced water from oil production will be directly discharged into the ocean, the predicted environmental concentrations (PECs) of the notified polymer in sea water has been calculated based on the CHARM model (Thatcher M. et al., 2005).

It is mentioned in the CHARM model that if the concentration of the chemical in produce water (C_{pw}) is known from experiments or produced water analysis, this value can be used as C_{pws}. The notifier has provided the concentration of the notified polymer in produced water (C_{pw}) from oil production. Therefore, C_{pw} is used as C_{pws} in the equation 1.

C_{pw} = 2 mg/L (provided by the notifier)

C_{pws} = concentration of the chemicals in the produced water including a safety factor (mg/L).

The PEC can be calculated using equation 1:

$$PEC = C_{pws} \times D_{distance\ x}$$

$$PEC = 2\ \mu g/L$$

in which:
PEC = Predicted Environmental Concentration of a chemical at a certain distance from the platform (mg/L),

$D_{distance\ x}$ = dilution factor at distance x from the platform (0-1).

The dilution factor at a distance of x = 500 m is set to a realistic worst case default value of 0.001.

The notifier has provided raw data required by the CHARM modelling for the off-shore application. The PEC has been calculated based on these data.

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