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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Luvicap 55 W

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 Ageing, 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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867)
500 Princes Highway
Noble Park, VIC 3174

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 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, Means of Identification, Polymer Constituents and Composition, Residual Monomers/Impurities, Use Details, Import Volume and Identity of Recipient.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point, Flammability, Autoignition Temperature, and Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA TSCA (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME
Luvicap 55 W (containing 50% of the notified polymer)

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

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >1000 Da

3. COMPOSITION

DEGREE OF PURITY >90%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Stable under normal conditions of use.

DEGRADATION PRODUCTS
Burning of the notified polymer is likely to release oxides of carbon and nitrogen.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellowish crystalline powder

Property	Value	Data Source/Justification
Melting Point	Not available	Predicted decomposition prior to melting
Boiling Point	Approximately 100°C*	MSDS
Density	1110 kg/m^3 at 20°C*	MSDS
Vapour Pressure	Not expected to be volatile	Based on the chemical structure of the polymer
Water Solubility	6.0 x 10^5 to 6.9 x 10^5 mg/kg at 23°C	Measured
Hydrolysis as a Function of pH	Hydrolytically stable at pH 4–9	Measured
Partition Coefficient (n-octanol/water)	log P_{ow} < 0 at 20°C	Measured**
Adsorption/Desorption	Not expected to strongly partition to solids from water	Based on the high water solubility and low partition coefficient
Dissociation Constant	Not expected to dissociate	Based on the absence of dissociable functional groups
Particle Size	Not determined	The notified polymer will only be imported in aqueous solution.*
Flash Point	Not determined	The notified polymer is a solid and will only be imported in aqueous solution.*
Flammability	Stable under normal use condition*	Estimated
Autoignition Temperature	Stable under normal use condition*	Estimated
Explosive Properties	Stable under normal use condition*	Estimated

* Based on properties of Luvicap 55 W which probably reflect those of the solvent (50% water).
** Test conducted using Luvicap 55 W, an aqueous solution of the notified polymer at a concentration of 50%.

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A. It should be noted that, in the water solubility study, high viscosity was observed in all test mixtures of the notified polymer and water in different ratios.

Reactivity

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

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will only be imported as an aqueous solution (Luvicap 55 W) in which the concentration of the notified polymer will be 50%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	3-10	10-30	30-50	50-100

PORT OF ENTRY

Fremantle WA

TRANSPORTATION AND PACKAGING

The solution of the notified polymer will be imported in 120 kg lined metal drums via sea. These will be transported via road to distributors' sites where they may be repackaged into 25 kg plastic kegs before transporting to end-users by road and sea.

USE
The notified polymer will be used as a hydrate inhibitor to prevent the formation of gas hydrates that can block pipelines. It will be used as imported (50% aqueous solution) for the pipelines connected to offshore oil platforms. The concentration of the notified polymer in oil/gas/water mixtures will be <1%.

OPERATION DESCRIPTION
No reformulation of the imported product will occur in Australia. Repackaging may occur before distribution to the end users depending on customer orders. During repackaging, 120 kg drums will be taken by a forklift from the storage area to a processing area where plastic taps will be fitted to each drum. The operator will then open the tap and fill the 25 kg plastic kegs.

At the offshore oil platforms, solution of the notified polymer will be pumped directly from the container/drum via an umbilical type cord into a well head, which is the top end of a oil well pipeline where the oil is removed from. An alternative addition will be via injection into the well head. Both methods of transfer will be enclosed systems. The notified polymer will be recovered in the water produced from oil production operations. This produced water will be automatically reinjected into geological formations for pressure maintenance without removal of the notified polymer.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

During repackaging of the imported solutions containing 50% of the notified polymer, dermal, ocular and inhalation exposure to workers may potentially occur during fitting the tap and during product filling if there is a distance between the tap and the opening of the keg. However, exposure to significant amounts of the notified polymer should be limited due to minimum manual handling, short exposure duration, and use of personal protective equipment (PPE) such as full-length overalls, nitrile gloves and safety glasses. In addition, the high viscosity of the notified polymer solution will prevent the generation of aerosols, and therefore, worker exposure from inhalation.

Exposure to the notified polymer during end use will be unlikely because of the enclosed processes, except during connection and disconnection of lines where dermal and/or ocular exposure may occur from accidental spills or splashes. However, the PPE worn by workers should limit any potential exposure.

6.1.2. Public exposure

The notified polymer is intended only for use in industry and as such public exposure to the notified polymer is not expected, except in the event of spills and leakages during transportation.

6.2. Human health effects assessment

The results from toxicological investigations conducted using the notified polymer and an acceptable analogue are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >5000 mg/kg bw; low toxicity
Rabbit, skin irritation (analogue)	irritating
Rabbit, eye irritation (analogue)	non-irritating

No data on toxicokinetics, metabolism and distribution were provided. Based on its properties, the notified polymer will have limited absorption via the skin, ocular, and inhalation due to its high water solubility (6.0 x 10^5 to 6.9 x 10^5 mg/kg) with low log P_{ow} (less than zero), and relatively high molecular weight, low vapour pressure, and high viscosity.

The notified polymer was found to be of low acute oral toxicity (LD50 >5000 mg/kg bw). No data on acute dermal and inhalation toxicity were provided.

Irritation studies were conducted using an analogue with an almost identical structure to the notified polymer. The skin irritation study indicated moderate to severe erythema that persisted until the end of the observation period (14 days) in all test animals. The analogue chemical was found to be not irritating to the eyes.

No data on sensitisation, repeated dose toxicity, genotoxicity and carcinogenicity were provided for the notified polymer. A literature search did not locate any toxicity data on both the notified polymer and the analogue. Therefore, the systemic toxicities are unknown. However, based on its limited systemic absorption and absence of structural alerts, the notified polymer is not expected to present significant systemic toxicity.

Classification
Based on the skin irritation data for an analogue with almost identical structure, the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on the available data, the notified polymer may present a risk of skin irritation to workers, especially during repackaging when fitting the tap and during end use at the offshore oil platform when connection and disconnection of transfer lines occur. However, this risk is expected to be limited due to low frequencies of these processes, short exposure duration, and use of PPE at workplaces. The enclosed nature of other processes will restrict any risk presented by the notified polymer. However, due to the severity of the skin irritation observed in animals, employers should implement appropriate control measures to minimise dermal exposure.

6.3.2. Public health

As there will be no exposure of the public to the notified polymer, the risk of skin irritation from the notified polymer is considered to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will not be manufactured in Australia. Release to the environment during shipping, transport and warehousing will only occur in the unlikely event of accidental spills or leaks from the 120 kg lined metal import drums. Repackaging of the notified polymer into 25 kg plastic kegs is also not expected to lead to releases to the environment, except through accidental spills. Such spills will be contained by bunding in the processing area. It is expected that not more than 1% of the imported quantity of notified polymer will remain in import containers after decanting. The used import containers will be sent to a drum reconditioner prior to disposal at a secure landfill site.

RELEASE OF CHEMICAL FROM USE
The injection of the notified polymer into the wellhead both beneath the sea level and at offshore oil production platforms is not expected to lead to releases to the environment except through accidental spills and/or leaks from the import drums and kegs or from the liquid transfer equipment. It is expected that not more than 1% of the imported quantity of notified polymer will remain in the import containers and kegs after transfer of the liquid product from these containers on the oil platform. It is anticipated that these used containers will be shipped on-shore and disposed of at a secure landfill site.

RELEASE OF CHEMICAL FROM DISPOSAL

The overwhelming majority of the quantity of notified polymer is expected to be disposed of and confined within the rock formations of depleted oil fields, as the notified polymer will be recovered in the produced water and reinjected into geological formations for pressure maintenance. Hence, no release of the notified polymer to the aquatic environment is anticipated from disposal at off-shore oil production sites.

7.1.2 Environmental fate

The notified polymer is not readily biodegradable, but there are some indications that it maybe slowly degraded by micro-organisms in seawater. However, it is not expected to be discharged to the aquatic environment in significant quantities based on the intended use pattern and disposal method. Some limited releases to the aquatic environment may occur as a result of the cleaning of import drums on-shore and discharge of the resulting aqueous wastes to the sewer. These limited quantities of notified polymer are expected to be eventually degraded in or removed from the water column by biotic and abiotic processes.

For the details of the environmental fate studies please refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

No significant concentrations of the notified polymer are expected in the aquatic environment based on the limited possibility for release which follows from the use of the polymer within the fluids handling systems of off-shore oil platforms and the ultimate disposal of the used polymer in depleted oil fields. The PEC for the notified polymer has therefore not been calculated.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted using Luvicap 55 W are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 hours)	LC50 >1000 mg/L	Not harmful to fish
Invertebrate Toxicity (48 hours)	LC50 484 mg/L	Not harmful to invertebrates
Algal Toxicity (72 hours)	E_rC50 145 mg/L	Not harmful to algae

The aquatic ecotoxicology test results indicate that the notified polymer is not harmful to marine organisms from the three trophic levels.

7.2.1 Predicted No-Effect Concentration

No significant aquatic exposure is anticipated based on the intended use and disposal method of the notified polymer. Hence, a Predicted No Effect Concentration (PNEC) was not calculated.

7.3. Environmental risk assessment

The notified polymer will not be released in significant quantities to the aquatic environment as it will be used within closed fluid handling systems of off-shore oil production platforms and will be disposed of within the geological formations of depleted oil fields. The possibility of significant exposure of aquatic organisms to the notified polymer is therefore low. Furthermore, the notified polymer is not harmful to any of the three trophic levels in the marine environment. On this basis, the environmental risk of the notified polymer is considered to be acceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data, the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

R38 Irritating to skin

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Skin irritation	Category 2	Causes skin irritation

Human health risk assessment
Under the conditions of the occupational settings described, together with the recommended control measures, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment
The notified polymer is not considered to pose a risk to the environment based on its reported use pattern, low potential for exposure of aquatic organisms, and its low toxicity to aquatic organisms.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified polymer:
  - R38 Irritating to skin

- The following safety phrases for the notified polymer are recommended:
  - S24: Avoid contact with skin
  - S28: After contact with skin, wash immediately with plenty of water
  - S36/37: Wear suitable protective clothing and gloves

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - ≥20%: R38 Irritating to skin

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - Prevent leaks and spills;
  - Wherever possible, direct handling of the notified polymer should be avoided; rather, some remote handling apparatus should be used;
  - Minimise manual processes.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Avoid contact with skin and contaminated clothing;
  - A shower should be available;
  - Avoid spills and splashing during use;
  - After exposure, any contaminated PPE should be thoroughly cleaned before re-use.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:

- Protective clothing;
- Chemical resistant gloves.

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The notified polymer should be disposed of by landfill.

- 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 chemical 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
- the notified polymer is imported in any form other than as an aqueous solution.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a hydrate inhibitor in oil and gas pipelines, or is likely to change significantly;
- the amount of chemical being introduced has increased from 100 tonnes, or is likely to increase, significantly;
- if the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical 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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 6.0×10^5 to 6.9×10^5 mg/kg at 23ºC

REMARKS The notified polymer and water were mixed in different ratios and rolled on a roller mixer at room temperature to estimate the solubility/miscibility. The miscibility of the notified polymer with demineralised H_2O was estimated visually. High viscosity was observed in all mixtures with different ratios.

Test Facility BASF (2007a)

Hydrolysis as a Function of pH Hydrolytically stable

Method OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (ºC)*	*Result*
4	50	$t_{1/2}$ > 1 year at 25°C
7	50	$t_{1/2}$ > 1 year at 25°C
9	50	$t_{1/2}$ > 1 year at 25°C

Remarks The hydrolytic stability of the notified polymer was evaluated by ^1H NMR spectroscopy in D_2O. No hydrolysis of the polymer was observed within 5 days at 50°C.

Test Facility BASF (2007a)

Partition Coefficient (n-octanol/water) $\log P_{ow} < 0$ at 20ºC

Method OECD TG 117 Partition Coefficient (n-octanol/water), High Performance Liquid Chromatography (HPLC) Method.
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks The test was conducted using Luvicap 55 W, an aqueous solution of the notified polymer at a concentration of 50%. Luvicap 55 W was not retained on the chromatographic column and the partition coefficient is therefore an estimated upper limit.

Test Facility AnalyCen Ecotox (2005a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 2004/73/EC B.1tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Sprague-Dawley Rj:SD
Vehicle	Purified water
Remarks - Method	No significant deviations from the test protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	1 female	5000	0
II	2 females	5000	0

LD50	>5000 mg/kg bw
Signs of Toxicity	No mortality or clinical signs were observed.
Effects in Organs	The body weight gain of the test animals was not affected by treatment. At necropsy, no abnormalities were observed in any animals.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	BASF (2007b)

B.2. Irritation – skin

TEST SUBSTANCE	Analogue chemical (aqueous solution, concentration unknown)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive
Remarks - Method	No significant deviations from the test protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	1.3	1.7	2.7	3	>14 days	2
Oedema	0	0	0	1	<24 hours	0

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

Remarks - Results	Well-defined erythema observed in 2 test animals at the beginning of the test lasted for at least 48 hours and the severity reduced to mild erythema till the end of the observation period. In the third test animal, moderate to severe erythema were found from 1 hour after the treatment and lasted for at least 48 hours. The severity reduced to well-defined from 72 hours but persisted till the end of the test.

CONCLUSION Based on these results for the analogue polymer, the notified polymer is considered to be irritating to the skin.

TEST FACILITY BASF (1998a)

B.3. Irritation – eye

TEST SUBSTANCE Analogue chemical (aqueous solution, concentration unknown)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	72 hours
Remarks - Method	No significant deviations from the test protocol.

RESULTS

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

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal. NA, not applicable.

Remarks - Results Moderate conjunctiva redness and chemosis were observed in some of the test animals 1 hour following the treatment, but disappeared or eased 24 hours after administration of the test substance. Mild conjunctiva redness was observed in all 3 animals by 24 hours, but this effect disappeared within 48 hours.

CONCLUSION Based on these results for the analogue polymer, the notified polymer is considered to be non-irritating to the eye.

TEST FACILITY BASF (1998b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

All tests listed below were conducted using Luvicap 55 W, an aqueous solution of the notified polymer at a concentration of 50%.

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Luvicap 55 W
METHOD	OECD TG 301 A Ready Biodegradability: DOC Die-Away Test.
Inoculum	Washed and sieved activated sludge from the aeration tank of a municipal wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The Dissolved Organic Carbon concentration (DOC) was monitored by an unspecified method
Remarks - Method	The notified polymer in the test solutions was obtained by dilution of Luvicap 55 W in deionised water and mineral salt medium. The DOC concentration of the notified polymer and the reference substance (aniline) at test initiation was 20 mg/L.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
1	-2	1	2
3	-2	3	9
5	3	5	97
7	1	7	96
10	-10	10	93
28	-10	28	98

Remarks - Results	The removal of DOC was 97% complete in the reference substance test solution 5 days after test initiation. The removal of DOC was 51% complete over the same period in the toxicity control solution. In both cases, biodegradation was complete after the first 5 days of the test. The test is therefore valid and the notified polymer does not appear to inhibit biodegradation. The DOC concentration of the notified polymer increased modestly over the course of the test. This increase appears to be an experimental artefact and biodegradation of the notified polymer clearly did not occur.
CONCLUSION	The notified polymer is not readily biodegradable.
TEST FACILITY	BASF (2006)

C.1.2 Biodegradability in seawater

TEST SUBSTANCE	Luvicap 55 W
METHOD	OECD TG 306 Biodegradability in Seawater – Closed Bottle Method
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	The oxygen concentration was measured electrochemically.
Remarks - Method	The test was carried out in decanted and aged seawater with an initial

microbial colony count of 6×10^3 cfu/ml.

The biodegradation of the test substance was evaluated at a single test concentration of 2.4 mg/L. The chemical oxygen demand (COD) of the notified polymer was determined experimentally as 1.06 mg O_2/mg test substance. The concentration of the reference substance (sodium benzoate) used in the inoculum and toxicity control solutions was 2.0 mg/L.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	2	7	73
14	4	14	76
21	2	21	75
28	0	28	75

Remarks - Results

The biodegradation of the reference substance was 73% complete within 7 days of test initiation, which is consistent with the validity criteria for this test. The physico-chemical parameters of the test solutions also remained within the recommended ranges. The test is therefore valid.

The biological oxygen demand (BOD) in the toxicity control samples was equal to the sum of the BODs for the reference and test substances, which confirms that the notified polymer does not inhibit bacteria at this concentration.

The extent of the biodegradation of the notified polymer is low and variable in this test, which indicates that this substance is not easily biodegradable in seawater at this concentration.

CONCLUSION

The notified polymer is not easily biodegradable in seawater.

TEST FACILITY

AnalyCen Ecotox (2005b)

C.1.2. Bioaccumulation

Remarks

The partition coefficient of the notified polymer is low and its water solubility is high. These physical properties together with the chemical structure of the notified polymer indicate that it will be unlikely to partition into biological membranes. The notified polymer is therefore not expected to bioaccumulate.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE

Luvicap 55 W

METHOD

PARCOM 1995 Part B Protocol for a Fish Acute Toxicity Test (modified OECD TG 203 Fish, Acute Toxicity Test – (Semi-static)).

Species	Sheepshead minnow (*Cyprinodon variegatus*) – juvenile
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	Saltwater with salinity in the range 3.3–3.4% was used as the test medium
Analytical Monitoring	None
Remarks – Method	The notified polymer in the test solutions was obtained by dilution of Luvicap 55 W in the saltwater test medium. The test solutions were renewed 48 hours after test initiation.

The positive toxicity control substance, 3,5-dichlorophenol, was used to assess the sensitivity of the fish to toxic substances at a single test concentration of 2.3 mg/L (nominal).

RESULTS

Concentration mg/L (nominal)	*Number of Fish*	*Mortality*			
		24 h	*48 h*	*72 h*	*96 h*
Control	10	0	0	0	0
100	10	0	0	0	0
300	10	0	0	0	0
1000	10	0	0	0	0

LC50	>1000 mg/L at 24 hours. >1000 mg/L at 48 hours. >1000 mg/L at 72 hours. >1000 mg/L at 96 hours.
NOEC	1000 mg/L at 96 hours.
Remarks – Results	The mortality in fish exposed to the toxicity control was 40% after 96 hours. The concentration of the notified polymer was not measured. However, as this polymer is highly water soluble and the test solutions were renewed after 48 hours, the nominal exposure concentrations are likely to correspond relatively closely to the actual concentrations of polymer that fish were exposed to during the test. The notified polymer had no lethal effects on the fish in this test up to the maximum test concentration. Hence, no acute toxicity metrics could be derived.

CONCLUSION — The notified polymer is not harmful to fish.

TEST FACILITY — AnalyCen Ecotox (2005c)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE — Luvicap 55 W

METHOD	ISO/CD 14669: Determination of Acute Lethal Toxicity to Marine Copepods. PARCOM Ring Test Protocol: Acute Toxicity to the Marine Copepod *Acartia tonsa*.
Species	*Acartia tonsa*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Unspecified. The test medium was filtered and aerated seawater.
Analytical Monitoring	None
Remarks - Method	The notified polymer was obtained in the test solutions by dilution of Luvicap 55 W. The sensitivity of the copepods to toxic substances was assessed with 3,5-dichlorophenol at a nominal test concentration of 1.0 mg/L.

RESULTS

Concentration mg/L (Nominal)	*Number of A. tonsa*	*Mortalities*	
		24 h	*48 h*
Control	4 × 5	0	0
100	4 × 5	0	0
250	4 × 5	0	0
500	4 × 5	0(A), 2(B), 3(C), 2(D)*	3(A), 4(B), 3(C), 3(D)*
1000	4 × 5	20	20

* The descriptors (A), (B), (C), (D) refer to duplicate test Vessels 1, 2, 3, and 4, respectively, which each contained 5 copepods initially.

LC50	516 mg/L at 24 hours 484 mg/L at 48 hours
NOEC	250 mg/L at 48 hours
Remarks - Results	The lethality of the positive control to the copepods was 70% after 48 hours, which is consistent with the validity criteria of the test method. The acute toxicity end points were calculated from the respective dose-response curves; however, there were insufficient data to calculate confidence intervals for these metrics.

CONCLUSION — The notified polymer is not harmful to invertebrates.

TEST FACILITY — AnalyCen Ecotox (2005d)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE — Luvicap 55 W

METHOD — ISO 102 53: Water Quality Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum*.

Species	*Skeletonema costatum*
Exposure Period	72 hours
Concentration Range	Nominal: 25, 100, 250, and 1000 mg/L
Auxiliary Solvent	None
Water Hardness	Unspecified
Analytical Monitoring	None
Remarks - Method	The notified polymer in the test solutions was obtained by dilution of Luvicap 55 W in algal growth medium. The sensitivity of the diatoms to toxic substances was assessed with 3,5-dichlorophenol at a nominal test concentration of 1.5 mg/L.

RESULTS

Growth	
E_rC50 mg/L at 72 h	*NOE_rC mg/L*
145 (nominal)	100 (nominal)

Remarks - Results	The inhibition of growth rate in the positive control test was 40% after 72 hours, which is consistent with the validity criteria of this test method. The difference in algal growth rate between the control and the two lowest nominal test concentrations was not statistically significant after 72 hours. However, the calculated growth rate for algae exposed to the two highest nominal test concentrations (250 and 1000 mg/L) was

	negative after 72 hours. For the purposes of analysis, these negative growth rates were approximated as 100% growth rate inhibition and the EC50 was estimated from a dose-response curve that was plotted using these combined data. The negative growth rates observed in this test indicate that the notified polymer has some algaecidal activity at high nominal concentrations.
CONCLUSION	The notified polymer is not harmful to algae.
TEST FACILITY	AnalyCen Ecotox (2005e)

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