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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in A-5D

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FULL PUBLIC REPORT

Polymer in A-5D

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

OFB Flexible Solutions Distribution of Australia Pty Ltd (ACN: 116 511 034 1)

Unit 3, 27 Jeays St

Bowen Hills QLD 4006

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater 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 No.

Structural Formula

Molecular Formula

Polymer constituents

Import volume

Identity of recipient

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None.

NOTIFICATION IN OTHER COUNTRIES

CEFAS (The Centre for Environment, Fisheries & Aquaculture Science) UK (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

A-5D, SCI-5C (aqueous solutions containing the notified polymer).

METHODS OF DETECTION AND DETERMINATION

METHOD IR spectroscopy

Remarks Peaks consistent with proposed structure.

TEST FACILITY In-house.

METHOD Titration based on turbidity measurement.

Remarks None.
TEST FACILITY In-house.

3. COMPOSITION

DEGREE OF PURITY

> 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None

ADDITIVES/ADJUVANTS

None

DEGRADATION PRODUCTS

The notified polymer is stable under normal conditions of use.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The polymer contains only trace levels of residual monomers.

4. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years

The notified polymer will not be manufactured in Australia but will be imported by Wharf into Western Australia at a concentration of up to 40%. It will be transported by road for storage at a warehouse until required.

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

Year	1	2	3	4	5
Tonnes	10-30	10-30	10-30	10-30	10-30

USE

The notified polymer will be used as a scale inhibitor (to prevent the scale formation such as calcium carbonate or barium sulfate) in on and offshore oil field applications.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

The notified polymer will initially be imported through Fremantle, Western Australia

IDENTITY OF MANUFACTURER/RECIPIENTS

The notified polymer will initially be stored in the notifier's customer site located in Kwinana.

TRANSPORTATION AND PACKAGING

Products containing the notified polymer at up to 40% are imported directly by ship and transported by road to the site for distribution and/or potential repacking. Finished products containing the notified polymer are transported by road in its original packaging (1000 L Intermediate Bulk Container (IBC) and/or 200 L drums) to customers in Western Australia as required.

5.2. Operation description

The notified polymer is not currently reformulated, however there is potential to reformulate. The operation description provided by the notifier for reformulation below is consistent with the potential customer base. Initially no repackaging is expected to occur either.

Reformulation

During the reformulation process, the imported product containing the notified polymer (up to 40%) will be moved from the storage facility by forklift and transferred to a blending tank via insertion of a dip tube and use of automated pumps. The mixing process is automated and occurs in a closed system. QC sampling occurs after mixing, samples of approximately 200 mL size will be taken. Once the mixing is finished, the resultant product containing the notified polymer (5–40%) is filled into drums or

IBCs. Drumming of the finished product directly from the blending tank or from storage tanks can be automated or can involve the manual connection and disconnection of filling lines. The resultant products will be transferred to the warehouse for storage until required.

End user operation in Australia – Oil Production:

The notifier advises that products containing the notified polymer (5–40%) will be dosed to into production flowlines upstream of the Electronically Submersible Pumps (ESP) via a stainless steel umbilical line which runs from the Onshore plant to the unmanned Offshore platform and then down to the ESP's on the ocean floor. The produced oil/water flows back onshore and into a oil/water separator and settling tanks. The produced water is combined with water from Onshore bores and sent offshore by booster pumps via the water reinjection pipeline. The two water re-injection wells carry the water back down to the formation at a different location from the producing wells to "sweep" the oil from the formation and maintain reservoir pressure. This application is known as a zero water discharge set-up No production water is released into the ocean. Produced oil containing trace quantities of the notified polymer <0.01% is transported to oil refineries within Western Australia and blended off with other crude oil (from various sources both locally and internationally) to be used as feedstock for the refinery.

The dosage of product containing the notified polymer required for oil field application will be determined after field trials. Generally speaking, the amount required for scale inhibition is about 0.0005% to 0.01% as product depending on the severity of the field condition.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	Number	Exposure Duration	Exposure Frequency
Manager	1	1 hour/month	1 month/year
Warehouse	1	1 hour/month	1 month/year
Quality control	1	1 hour/month	1 month/year
Process operator	2	2 hour/month	1 month/year
End Users	3	2 hour/day	365 days/year

Exposure Details

Import, transport and storage:

Exposure is not expected during import, transport or storage operations except in unlikely cases of accidental puncture of transport or storage containers.

Reformulation and Repacking imported product

Potential routes of exposure include dermal and accidental ocular exposure as a result of spills and splashes and contact with the dip tube during transfer of the notified polymer via pump from drums and IBCs to a closed blending vessel. Dermal or ocular exposure to the notified polymer may also occur during cleaning of the blending vessel or transfer lines. Concentration of notified polymer during such operations is 5-40% and potential exposure will be mitigated by the use of PPE.

Quality Control

Sampling and analysis of imported and manufactured products containing the notified polymer may result in potential dermal and accidental ocular exposure of 5-40% notified polymer as a result of accidental spills and splashes. Potential exposure will be mitigated by the use of PPE.

End user operation in Australia - Oil Production:

The following exposure scenario is typical at oil refineries within Australia: Potential routes of exposure include dermal and accidental ocular exposure as a result of manual attaching and detaching transfer lines (containing 5-40% of the notified polymer). Potential exposure will be mitigated by the use of PPE. The dosing process is fully enclosed and as such exposure is expected to be negligible. Appropriate containment procedures (such as catching pans) and engineering controls (local exhaust ventilation) are expected to be in place at the refineries. Workers will wear personal protective equipment such as safety glasses, gloves and overalls. Exposure to the notified polymer in the final blended fuel will be up to 0.01%.

While the notifier provides no specific details, petrol station workers may be potentially exposed to diluted notified polymer up to 0.01% in fuel during fuel handling activities and maintenance of automotive fuel systems.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified polymer is manufactured overseas and will be imported directly as a solid aqueous solution to the customer sites for use in offshore oil production. At a later stage, the imported product will be reformulated in Australia.

During the reformulation process, the required amount of the notified polymer from the drums or IBC containers will be blended with water or other oil field polymers in a closed blending vessel. Final product will be transferred from the blending vessel back to the drums or IBC. The drums will go to landfill or be recycled. It is expected that <0.1% of residues will be left in the IBC container. Any residues from transfer lines pumps etc will be handled by Kwinana's effluent system. No release, unless accidental, of product containing notified substance, is expected at the customer site. Some residues from empty drums or IBC will be transported back to the customer sites for washing, recycling or landfill.

RELEASE OF CHEMICAL FROM USE

The product will be used in the oil field application by professional engineers. The application is a zero water discharge set-up. The notified polymer will be injected into the production flowlines upstream of the Electronically Submersible Pumps (ESP's) via a stainless steel umbilical line which will run approximately 16 km from the Onshore Plant to the unmanned offshore platform and then down to the ESP's on the ocean floor. It is expected that the notified polymer will partition (>>99%) into the aqueous phase.

The produced water, that comes from the offshore production wells, is separated from the oil and gas at the Arrowsmith Stabilisation Plant onshore via large separators and settling tanks. It then combines with bore water from onshore bores and is then sent offshore by booster pumps via the water reinjection pipeline. The two water re-injection wells carry the water back down into the formation at a different location from the producing wells to "sweep" the oil from formation and maintain reservoir pressure. There is no water being discharged into the sea offshore. It all gets re-injected back down into the formation via water re-injection wells.

Any notified polymer that ends up in the oil will be transported to the refinery and be blended off with other crude oil to be used as feedstock for the refinery. Therefore, it is expected that very small amount of the notified polymer (< 0.01%) will end up in feedstock and be consumed with it.

5.5. Disposal

Drums containing residual polymer will go to landfill or be recycled. Any small residual from transfer lines, pumps etc will be handled by Kwinana's effluent system. The Kwinana site is licensed by the EPA to spray irrigate with wastewater providing the latter contains less than 2500 ppm solids.

5.6. Public exposure

The products containing the notified polymer will not be manufactured in Australia. The products (containing 5-40% notified polymer) will be used industrially in offshore oil production.

The potential for exposure of the general public to the notified polymer during normal industrial storage, handling, transportation and manufacturing processes will be minimal. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of the new polymer being released from the packaging and the public being exposed or contamination of the environment occurring.

While the notifier provides no specific details, the public may be potentially exposed to diluted notified polymer up to 0.01% in fuel during fuel handling activities and maintenance of automotive fuel systems.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is not isolated from solution. The following limited physicochemical properties have been provided for the product A-5D, an aqueous solution containing approximately 40% notified polymer.

Appearance at 20°C and 101.3 kPa Amber liquid

Freezing Point -8°C

METHOD OECD TG 102 Melting Point/Melting Range.

Remarks The sample was stirred and continuously cooled until the temperature readings

remained constant. The freezing point may vary from -5 to -20°C.

TEST FACILITY NanoChem Solutions Inc. (Year not stated)

Boiling Point

Remarks Test not conducted.

Density $1242 \text{ kg/m}^3 \text{ at } 25^{\circ}\text{C}$

METHOD OECD TG 109 Density of Liquids and Solids.

Remarks Hydrometer calibrated in accordance with ASTM E126. The density may vary from

 $1240-1280 \text{ kg/m}^3 \text{ at } 25^{\circ}\text{C}$

TEST FACILITY NanoChem Solutions Inc. (Year not stated)

Vapour Pressure Not determined

Remarks This has not been measured for the notified polymer, but it is expected to be very

low based on the structure due to the polymer's relatively high molecular weight

and anionic form.

Viscosity $\approx 0.04 \text{ Pa at } 25 \text{ }^{\circ}\text{C}$

METHOD In-house.

Remarks Conducted using a Brookfield viscometer.

TEST FACILITY NanoChem Solutions Inc.

Charge Density CEC=300 based on 40% solid (theoretical calculation)

Remarks Cation Exchange Capacity (CEC) based on calculation

Water Solubility >1000 g/L

METHOD In-house flask method.

Remarks Based on the preliminary test, an estimated quantity of the notified polymer was

dissolved in a certain amount of water in a closed vessel. The vessel was agitated at 30°C. After one day, the vessel was re-equilibrated for 24 h at 20°C and then centrifuged. The concentration of the test substance was determined by the Hyamine based (colourimetric method). The polymer was completely soluble in

water in all proportions.

TEST FACILITY NanoChem Solutions Inc. (Year not stated)

Hydrolysis as a Function of pH

METHOD Not stated

Remarks Solutions of thermal polyaspartate were stable at pH 8-9 for years at ambient

temperature. At pH 9-10 concentrated solutions of the notified polymer showed no

degradation in molecular weight (by GPC) after 48 h at 100° C. The stability of the notified polymer is lower at pH <6 and >12. A product stability study of 40% solutions of the notified polymer at pH 1-10 showed no significant degradation in molecular weight from pH 6 to 10 over a five week period at room temperature. At pH 1 the molecular weight had degraded from 5000 to about 3000 over 5 weeks.

TEST FACILITY Not stated

Partition Coefficient (n-octanol/water) log Pow <0

METHOD OECD TG 117 Partition Coefficient (n-octanol/water), HPLC Method.

Remarks The partition coefficient was estimated by the HPLC method. Six calibration

substances with reported log Po/w values were used to calibrate the measured capacity factor of the test substance. The test substance consisted of one compound corresponding to a single log Po/w value on the chromatogram which eluted before all the reference substances. Since the method was only suitable for the log Po/w range between 0 and 6, values calculated to <0 were defined as 0 in the

calculation of the weighted average.

TEST FACILITY AnalyCen Ecotox AS (2001)

Adsorption/Desorption

Not determined

Remarks The notified polymer is not expected to bind strongly to organic matter in soil due

to its expected solubility in water.

Dissociation Constant

Not determined

Remarks Because of the presence of the sodium salt, the notified polymer is expected to be

dissociated under the environmental pH range of 4-9, except at the lower end of

this range.

Particle Size Test not conducted. The notified polymer is introduced in

liquid.

Flash Point

Remarks Test not conducted. The notified polymer is imported only as an aqueous solution.

Flammability

Remarks Test not conducted. The notified polymer is imported only as an aqueous solution.

Autoignition Temperature

Remarks Test not conducted. The notified polymer is imported only as an aqueous solution.

Explosive Properties

Remarks Test not conducted. The notified polymer contains functional groups which may

infer explosive properties, however, polymers containing similar structural units

have not been found to be explosive.

Stability Testing Stable in air. The notified polymer degrades to lower

molecular weight oligomers if the temperature exceeds

100°C.

METHOD In-house.

Remarks Heat by oven. Molecular weight was determined by GPC.

TEST FACILITY NanoChem Solutions Inc.

Reactivity

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

notified polymer may have possible interactions with strong oxidizers.

7. TOXICOLOGICAL INVESTIGATIONS

The notified polymer is not isolated from solution. The product A-5D is an aqueous solution containing approximately 40% notified polymer. The following toxicological data were based on studies performed on the product A-5D.

Endpoint	Result and Assessment Conclusion
Rat, acute oral	LD50>5000 mg/kg bw, low toxicity
Rat, acute dermal	LD50>5000 mg/kg bw, low toxicity
Rat, acute inhalation	LC50>5.1 mg/L/4, hour low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating

7.1.1 Acute toxicity – oral

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.

Species/Strain Rat/Sprague-Dawley

Vehicle Test substance administered as supplied.

Remarks - Method Statement of GLP.

RESULTS

Group	Number and Sex	Dose	Mortality		
	of Animals	mg/kg bw			
I	5 males	5000	0/5		
II	5 females	5000	0/5		
LD50	> 5000 mg/kg bw				
Signs of Toxicity	Lethargy and hunch had reversed by Day		ring the first five hours but		
Effects in Organs	No macroscopic fine	dings were recorded at nec	ropsy.		
Remarks - Results	There were no deaths or remarkable body weight changes during the study period.				
CONCLUSION	The test substance is	s of low toxicity via the ora	al route.		
TEST FACILITY	IIT Research Institu	te (1990)			

7.1.2 Acute toxicity – oral

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.

Species/Strain Rat/Sprague-Dawley
Vehicle Distilled water
Remarks - Method Statement of GLP.

RESULTS

Group	Number and Sex	Dose	Mortality
	of Animals	mg/kg bw	
I	5 males	5000	0/5
II	5 females	5000	0/5

LD50 > 5000 mg/kg bw

Signs of Toxicity Diarrhoea was noted in all test animals at 4 hours but had reversed by 24

hours. Soiling of the anogenital area was noted in 8/10 animals at 4 hours but had reversed by 48 hours in all but one animal. Wetness of the anogenital area was observed in 3/10 animals at 2 hours and 9/10 animals at 4 hours but had reversed by 24 hours. Soiling of the body areas was observed in 2/10 animals at 4 hours but had reversed by 24 hours. Alopecia of the anogenital area was observed in 1/10 animals on day 3

and continued until day 11 but revered by day 12.

Effects in Organs No macroscopic findings were recorded at necropsy.

Remarks - Results There were no deaths or remarkable body weight changes during the

study period.

CONCLUSION The test substance is of low toxicity via the oral route.

TEST FACILITY MB Research Laboratories (1996)

7.2. Acute toxicity – inhalation

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD OECD TG 403 Acute Inhalation Toxicity.

OECD TG 403 Acute Inhalation Toxicity – Limit Test.

EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation). EC Directive 92/69/EEC, 93/21/EEC B.2 Acute Toxicity (Inhalation) –

Limit Test.

Species/Strain Rat/Wistar Albino

Vehicle Test substance administered as supplied

Method of Exposure Whole-body exposure

Exposure Period 4 hours

Physical Form particulate aerosol

Particle Size Mass median diameter 1.15 µm

Remarks - Method Statement of GLP.

An aerosol was produced using a spraying systems nozzle model in

conjunction with a continuous infusion syringe pump.

RESULTS

Group	Number and Sex of Animals	Concentration <mg l=""></mg>		Mortality		
	-	Nominal	Actual			
I	5 males	62.5	5.1	0/5		
II	5 females	62.5	5.1	0/5		
LC50	>5.1 mg/L/4 hou	ırs				
Signs of Toxicity	Wetness, red sta	Wetness, red staining of the nose/mouth area, licking of the inside of				

mouth and test article coated fur were noted in Group I and II animals during the exposure period. During the observation period coating of fur with the test article, red staining of the nose/mouth area, brown staining of the ears, piloerection and alopecia were noted in some animals.

Effects in Organs No macroscopic findings were recorded at necropsy.

Remarks - Results There were no deaths during the study period. There were no remarkable

body weight changes in 8/10 animals, however one female lost weight during the first week and one female lost weight during the last week.

CONCLUSION The test substance is of low toxicity via inhalation.

TEST FACILITY MB Research Laboratories (1993)

7.3. Irritation – skin

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain Rabbit/New Zealand Albino

Number of Animals 6 females

Vehicle Test substance administered as supplied.

Observation Period 72 hours
Type of Dressing Semi-occlusive.
Remarks - Method Statement of GLP.

RESULTS

Lesion	Mean Score*	Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
Erythema/Eschar	0	0	-	-
Oedema	0	0	-	-

^{*}Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results No irritant or corrosive effects were noted on the treated skin of any

animal. There were no deaths or test substance related clinical signs

during the study period.

CONCLUSION The test substance is non-irritating to the skin.

TEST FACILITY MB Research Laboratories (1992)

7.4. Irritation – eye

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain Rabbit/New Zealand White

Number of Animals 6 females Observation Period 3 days

Remarks - Method Statement of GLP.

Fluorescein dye was used to facilitate corneal observations.

No significant protocol deviations although only limited details regarding

housing conditions were given.

RESULTS

Lesion	Mean Score*	Maximum Value	Maximum Duration of Any Effect	Maximum Value at End of Observation Period
Conjunctiva: redness	0	1	<24 h	0
Conjunctiva: chemosis	0	0	-	-
Conjunctiva: discharge	0	0	-	-
Corneal opacity	0	0	-	-
Iridial inflammation	0	0	-	-

^{*}Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

hour observation period but had reversed by 24 hours. Yellow nasal discharge was noted in one animal during the study period but no details regarding this observation were available such as time it occurred and duration of effect.

CONCLUSION The test substance is slightly irritating to the eye.

TEST FACILITY MB Research Laboratories (1993)

8. ENVIRONMENT

The notified polymer is not isolated from solution. The product A-5D is an aqueous solution containing approximately 40% notified polymer. The following environment fate and ecotoxicity data were based on studies performed on the product A-5D.

8.1. Environmental fate

8.1.1. Inherent biodegradability

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD OECD Test Guideline 302 B (Zahn Wellens Test)

Inoculum Activated sludge from the aeration tank of a municipal biological sewage

treatment plant.

Exposure Period 28 days
Auxiliary Solvent None
Analytical Monitoring DOC

Remarks – Method Activated sludge, mineral nutrients and test substance in aqueous medium

were contained in a glass vessel at the test concentration of 200 mg C/L. The mixture was agitated and aerated at 20-25°C in the dark or in diffuse light for up to 28 days. Blank controls, containing activated sludge and mineral nutrients were run in parallel. The biodegradation process was monitored by the determination of DOC values in filtered samples taken at regular time intervals. Diethylene glycol was used as the reference to

validate the test.

RESULTS

Test substance		Diethylene glycol		
Day	Mean % Degradation	Day	% Degradation	
7	24	7	98	
14	61	14	98	
21	83	21	100	
28	85	28	100	

Remarks – Results 83-87% of the test substance was degraded within 28 days of the test

period calculated based on DOC determination. The results were valid based on the degradation profile of the reference which had reached the

70% DOC removal within 14 days.

CONCLUSION The test substance is considered to be inherently biodegradable.

TEST FACILITY Cognis (1993)

8.1.2. Aerobic biodegradability

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD OECD Test Guideline 306 Biodegradability in Sea Water - Shake Flask

Method

Inoculum Nutrient fortified sea water

Exposure Period 60 days Auxiliary Solvent None Analytical Monitoring DOC

medium (nutrient-fortified sea water) to yield an approximate test concentration of 22 mg DOC/L. The solution of the test substance in the test medium was incubated under aerobic conditions in the dark or diffuse light at a temperature of 20°C. Biodegradation was followed by DOC

determination up to 60 days. Blank controls, containing sea water and sea water plus reference polymer, were used in the test. In addition, seawater plus reference polymer and test substance was used as an inhibitory test. The reference substance sodium benzoate at 27.9 mg DOC/L was used to validate the test.

RESULTS

Test substance		Sodium benzoate		
Day	DOC removal (mg/L)	Day	DOC removal (mg/L)	
3	5.8	3	0.0	
7	38.1	7	47.0	
14	41.2	14	73.2	
21	40.7	21	92.0	
28	28.2	28	94.2	
42	32.1			
60	34.0			

Remarks - Results

The results indicate that biodegradation had reached a maximum of 41% during the test period. It was observed that there was a negative shift in the biodegradation curves. Sampling was continued up to 60 days after the test and the DOC removal had clearly reached a plateau. An inhibitory test indicated that the test substance was only very slightly inhibitory towards the end of the test period and thus would not be classified as inhibitory at the test concentrations used.

CONCLUSION

The test substance is not readily biodegradable in seawater but is considered to be inherently biodegradable.

TEST FACILITY

Terra Environment (1999)

8.1.3. Bioaccumulation

Based on the negative log Po/w and the high molecular weight (NAMW >1000), the notified polymer is unlikely to cross biological membranes and have the potential for bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1.1. Acute toxicity to fish

Remarks - Method

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD Oslo and Paris Commission Guidelines (1995) "Protocol for fish acute

toxicity test"

Species Turbot (Scophthalmus maximus)

Exposure Period 96 h
Auxiliary Solvent None
Water Hardness None
Analytical Monitoring None

Based on the range finding test, a definitive test at a nominal concentration of 1000 mg/L was used for an exposure period of 96 h. Ten fish were assigned to the test vessel and the control vessel. All the test media were renewed approximately 48 h. The condition and behaviour of the fish were noted after 24, 48, 72 and 96 h, together with the appearance of the test medium. Before the start of the test, the water quality (dissolved oxygen, pH and temperature) were measured and at 24

h intervals thereafter.

RESULTS

Concentration mg/L Number of Fish Mortality

Nominal		24 h	48 h	72 h	96 h
0 (Control)	10	0	0	0	0
1000	10	0	0	0	0

LC50 >1000 mg/L at 96 hours based on whole product

>400 mg/L at 96 hours based on 40% notified polymer

NOEC 1000 mg/L at 96 hours based on whole product

Remarks – Results

All the animals survived at the test concentration

All the animals survived at the test concentration of 1000 mg/L. There was some erratic swimming and hyperventilation during the first 48 h but all fish appeared normal during the latter half of the test. Throughout the test the test media were yellow solutions. The water quality (dissolved

oxygen, pH and temperature) were within acceptable limits.

CONCLUSION The test substance is considered practically non-toxic to fish.

TEST FACILITY Fawley Aquatic Research Laboratories Ltd (1999)

Another study was performed on the product S12-21, which was reported to be similar to A-5D containing 40% notified polymer.

8.2.1.2. Acute toxicity to fish

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD No Test Guideline was cited

Species Fathead minnow (Pimephales promelas)

Exposure Period 48 h Auxiliary Solvent None

Water Hardness 78 CaCO₃ mg/L

Analytical Monitoring None

Remarks – Method The test was performed at nominal concentrations of 0, 625, 1250, 2500

and 10000 mg/L for an exposure period of 48 h. Duplicates of ten fish were assigned to each test concentration and the control. Mortalities of the fish were noted after 24 and 48 h. The water quality (dissolved oxygen, pH and temperature) were measured at 0, 24 and 48 h during the

test.

RESULTS

Concentration mg/L	Number of Fish	Mortality	
Nominal		24 h	48 h
0 (Control)	20	0	2
625	20	1	2
1250	20	5	7
2500	20	6	8
5000	20	19	20
10000	20	20	20

LC50 2117 mg/L at 96 hours based on whole product

846 mg/L at 96 hours based on 40% notified polymer

NOEC Not determined

Remarks – Results The 48 h LC50 was determined to be 2117 mg/L by the Spearman Karber

method. The NOEC was not determined as deaths occurred at the lowest test concentration. The water quality (dissolved oxygen, pH and

temperature) were within acceptable limits.

CONCLUSION The test substance is considered practically non-toxic to fish.

TEST FACILITY Shealy Environmental Services Inc. (1993)

8.2.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD Draft ISO Standard 14669 (1997) "Water quality determination of acute

lethal toxicity to marine copepods (Copepod, Crustacea)

Species Copepod (Acartia tonsa)

Exposure Period 48 hours
Auxiliary Solvent None
Water Hardness None
Analytical Monitoring None

Remarks - Method Based on the range finding test, nominal concentrations of 0, 125, 250,

500, 1000 and 2000 mg/L were used in the definitive test. The test was performed over 48 h duration without renewal of media at 20°C. the photoperiod was controlled to give 16 h light/8 h dark. Groups of five organisms (4 replicates) were allocated to each test concentration and control. The mortalities of the animals were recorded after approximately 24 and 48 h, as were observations of the appearance of the test media. A single concentration (1 mg/L, four replicates) of 3,5-dichlorophenol was tested alongside the test material. The water quality (dissolved oxygen,

pH and temperature) were measured throughout the test.

RESULTS

Concentration mg/L	Number of D. magna	% Mortality	
Nominal	, J	24 h	48 h
0 (control)	20	0	0
125	20	0	25
250	20	10	45
500	20	15	20
1000	20	10	20
2000	20	0	35
3, 5-dichlorophenol	20	70	80

LC50 >2000 mg/L at 48 hours based on whole product

>800 mg/L at 48 hours based on 40% notified polymer

NOEC Not determined

Remarks - Results The lowest concentration producing 100% mortality could not be

determined since there was 65% survival at the highest concentration employed after 48 h exposure. The NOEC could not be determined since there was 25% mortality at the lowest concentration employed after 48 h. 16 of the 20 test organisms were dead at the end of the 48 h for the reference. Throughout the test the test media were colourless solutions. The water quality (dissolved oxygen, pH and temperature) were within

acceptable limits throughout the test.

CONCLUSION The test substance is considered to be practically non-toxic to the

Copepod (Acartia tonsa), though some deaths occur at all levels tested.

TEST FACILITY Fawley Aquatic Research Laboratories Ltd (1999)

8.2.3.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD No Test Guideline was cited

Species Daphnia pulex

Exposure Period Auxiliary Solvent Water Hardness 48 hours None

78 CaCO₃ mg/L None

Analytical Monitoring

Remarks - Method

The test was performed at nominal concentrations of 625, 1250, 2500, 5000 and 10000 mg/L for an exposure period of 48 h. Four replicates of 5 test organisms were assigned to each test concentration and the control. Mortalities of the test organisms were noted after 24 and 48 h. The water quality (dissolved oxygen, pH and temperature) were measured at 0, 24 and 48 h throughout the test.

RESULTS

Concentration mg/L	Number of D. magna	Mortality	
Nominal	, J	24 h	48 h
0 (control)	20	0	1
625	20	0	1
1250	20	0	0
2500	20	9	19
5000	20	20	20
10000	20	20	20

LC50 1792 mg/L (CI: 1676-1917 mg/L) based on whole product

717 mg/L based on 40% notified polymer.

NOEC Not determined

NOEC was not determined, again due to deaths at the lowest concentration. The water quality (dissolved oxygen, pH and temperature)

were within acceptable limits.

CONCLUSION The test substance is considered to be practically non-toxic to Daphnia

pulex.

TEST FACILITY Shealy Environmental Services Inc. (1993)

8.2.3.2. Algal growth inhibition test

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD IS Standard 10253 (1997) "Water quality-marine algal growth inhibition

test with Skeletonema costatum and Phaeodactylum tricormutum"

Species Skeletonema costatum

Exposure Period 72 hours Concentration 1000 mg/L

Auxiliary Solvent None Water Hardness None Analytical Monitoring None

Remarks - Method Based on the range finding test, a limit test at nominal concentration of

1000 mg/L and a control were used. Seven flasks were set up for each test group and control group. Six test groups were used in the test and the remaining group was used for water quality determination. The test flasks were incubated at 20°C under constant white light. There was no renewal of test media during the 72 h duration of the test. pH and temperature were measured at the beginning and the end of the test. Samples were taken every 24 h and the number of cells counted using haemocytometer.

RESULTS

Biom	ass	Grov	vth
EbC50	NOEC	ErC50	NOEC
mg/L at 72 h	mg/L	mg/L at 72 h	mg/L
>1000		>1000	

Remarks - Results

As compared to the control there was no inhibition of growth rate or reduction of biomass at the test concentration of 1000 mg/L. NOEC could not be reliably reported as the final cell density and growth rate in the test level was greater than that of the control by more than 5%. The test was considered to be valid as the mean cell density for the control was greater than 16 times the initial cell density.

The test media were colourless solutions throughout the test. pHs and temperatures were within acceptable limits.

CONCLUSION The test substance is considered to be practically non-toxic to alga.

TEST FACILITY Fawley Aquatic Research Laboratories Ltd (1999)

Another study was performed on the product S12-21 which was reported to be similar to A-5D containing 40% notified polymer.

8.2.3 (ii). Algal growth inhibition test

TEST SUBSTANCE A-5D (40% notified polymer)

METHOD No Test Guideline was cited

Species Alga (Selenastrum capricornutum)

Exposure Period 96 hours

Concentration 6.25, 12.5, 25, 50, 100 mg/L

Auxiliary Solvent None Water Hardness None Analytical Monitoring None

Remarks - Method The test was performed at nominal concentrations ranging from 6.25-100

mg/L plus a control for an exposure period of 96 h under static condition. The test system was under continuous illumination at 25°C. The initial cell density in test chambers was 10,000 cells/mL. The growth was determined based on cell counts. The water quality (dissolved oxygen, pH

and temperature) were measured throughout the test.

RESULTS

Gr	rowth
LOEC	NOEC
mg/L at 72 h	mg/L
125	62.5

Remarks - Results The test was performed under chronic conditions for an exposure period

of 96 h. Statistical analysis was performed to determine the MATC. Based on the values of LOEC and NOEC, the MATC was calculated to be 88.4 mg/L. The water quality (dissolved oxygen, pH and temperature)

were within acceptable limits throughout the test.

CONCLUSION The test substance is considered to be practically non-toxic to alga.

TEST FACILITY Shealy Environmental Services Inc. (1993)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer is to be used in oil field production and is highly soluble in water. It is considered to be inherently biodegradable. The notified polymer showed no significant degradation in molecular weight from pH 6 to 10 over a five week period at room temperature. It has a negative log Pow indicating that it is likely to associate with the aqueous phase following its use in the oil field application. Its high molecular weight indicates that it is unlikely to cross biological membranes and bioaccumulate. It is anticipated that prolonged residence in an active landfill will eventually degrade the notified polymer via the biotic and abiotic processes.

During the reformulation process, any residues from transfer lines, pumps etc will be handled by Kwinana's effluent system. In the case of accidental spillage, there are established environmental controls to minimise exposure. It is expected that residues from empty drums or IBCs will be transported back to the customer sites for washing, recycling or landfill.

During its end use as an oil field application, there is no intentional discharge into the sea offshore, of the produced water containing the notified polymer that comes from the offshore production wells. Produced oil containing trace quantities of the notified polymer (<0.01%) is transported to oil refineries and blended off with other crude oil to be used as feedstock for refinery. Appropriate containment procedures and engineering controls are expected to be in place at the refineries to minimise exposure.

9.1.2. Environment – effects assessment

The results of the ecotoxicological data indicate that the test substance is practically non-toxic to aquatic life. The acute 48 h LC50 = 1792 mg/L for *Daphnia pulex* will be used as the toxicological end point.

Organism	Duration	Endpoint	Concentration (mg/L)
Turbot (Scophthalmus maximus)	96 h	LC50	>1000
Copepod (Acartia tonsa)	48 h	LC50	>2000
Alga (Skeletonema costatum)	72 h	EC50	>1000
Fathead minnows (Pimephales promelas)	48 h	LC50	2117
Daphnia magna	48 h	LC50	1792
Alga (Selenastrum capricornutum)	96 h	MATC	88.4

The Predicted No Effect Concentration (PNEC) is 17.9 mg/L, using a safety factor of 100 and the acute 48 h LC50 = 1792 mg/L for *Daphnia pulex*. As this is for the whole product, the PNEC for the notified polymer is 7.2 mg/L.

9.1.3. Environment – risk characterisation

Limited environmental release of the notified polymer is anticipated during the reformulation of the product. Even in the case accidental spillage, there are established environmental controls in place to minimise exposure. Residues remaining in containers are expected to be recovered or disposed of by landfill. In the oil field application, there will be no discharge of "produced water" to the ocean except for leaks or accidental spills. The amount required for scale inhibition is expected to be low (0.0005-0.01%). Any leaks will be further diluted in the ocean and unlikely to cause toxic effects to the aquatic organisms. Based on the low toxicity, there is expected to be sufficient safety margin as a result of unintentional discharge to the ocean. Any residues that reside in the produced oil will eventually be consumed as feedstock in the refinery.

Therefore, the notified polymer is unlike to pose an environmental risk under the proposed use pattern.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified polymer is imported in a product at up to 40%. Exposure during transport and storage would only occur through accidental breaching of the transport containers containing products in which the notified polymer is a component.

Processes involving the notified polymer are largely automated/enclosed, which will limit exposure to the notified polymer. However dermal and accidental ocular exposure to the notified polymer (up to 40%) could occur during repacking, reformulation, quality control, testing of dose lines and connection and disconnection of dose lines at oil production sites. The use of PPE such as gloves, coveralls and safety eye protection will mitigate exposure to the notified polymer.

Negligible exposure to petrol station workers is expected due to the low predicted concentration of the notified polymer in the fuel (0.01%).

9.2.2. Public health – exposure assessment

The notified polymer is for industrial use only. Public exposure to the products containing the notified polymer is only anticipated in the event of a spill during transport and storage through accidental breaching of the transport containers containing the notified polymer. No public exposure is expected through the use of the polymer in oil production. Negligible exposure to public is expected as a result of fuel handling due to the low predicted concentration of the notified polymer in the fuel (<0.01%).

9.2.3. Human health – effects assessment

Based on the negative log Pow and the high molecular weight the notified polymer is not expected to significantly cross biological membranes. The notified polymer as introduced is of low acute oral toxicity, low inhalation toxicity, non-irritating to the skin and slightly irritating to the eye. Based on these studies, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety - risk characterisation

The risk to workers from dermal and ocular exposure is considered to be low due to the limited exposure expected and the predicted hazard of the polymer via these routes. Any risk of slight irritant effects would be mitigated by the use of PPE.

Overall, due to the limited exposure expected and the likely low hazard of the notified polymer the risk to workers is expected to be low.

9.2.5. Public health - risk characterisation

Due to the likely low hazard of the notified and negligible public exposure to the notified polymer the overall risk to the public is expected to be low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES
Occupational Health and Safety

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

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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

• The notified polymer should be disposed of by landfill.

Emergency procedures

• Spills or accidental release of the notified polymer should be contained with an absorbent material and dispose of in accordance with federal, state and local regulations.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment 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
 - there is a significant release into the soil and aquatic environments from the proposed use in oil field application.

or

- (2) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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