

File No: EX/123 (LTD/1374)

February 2009

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer component 2 in Dodiflow 5735

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

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FULL PUBLIC REPORT**Polymer component 2 in Dodiflow 5735**

This assessment report is for an extension of original assessment certificate for Polymer component 2 in Dodiflow 5735. Based on the submission of new information by the extension notifier, some sections of the original assessment report have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Holder of the original assessment certificate (No. 2806, 2807, LTD/1374):

BP Australia Pty Ltd (ABN 53 004 085 616)

360 Elizabeth Street

MELBOURNE VIC 3000

Clariant (Australia) Pty Ltd (ABN 30 069 435 552)

675 Warrigal Road

CHADSTONE VIC 3148

Applicant for an extension of the original assessment certificate:

Shell Company of Australia Ltd (ABN 46 004 610 459)

8 Redfern Road

HAWTHORN EAST VIC 3123

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Hydrolysis as a Function of pH, Use Details.

Extension Applicant:

Concentration of Dodiflow 5735 in diesel fuel.

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, Partition coefficient (n-octanol/water), Adsorption/Desorption, Dissociation constant, Particle size, Flammability limits, Autoignition temperature, Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

NOTIFICATION IN OTHER COUNTRIES

Korea

USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Dodiflow 5735

MOLECULAR WEIGHT
> 1000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY < 65%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

<i>Chemical Name</i>	Residual monomers	<i>Weight %</i>	> 30%
<i>Hazardous Properties</i>	R38 Irritating to skin. R41 Risk of serious damage to eyes. R52/53 Harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment.		

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Grey black viscous liquid (~50% notified polymer in solvent)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Will only be imported in diesel fuel.
Density	890 kg/m ³ at 20°C (see below)	MSDS
Vapour Pressure	Not determined	Estimated to be low based on high molecular weight and in solution throughout its lifecycle.
Water Solubility	< 1 g/L at 20°C	Measured
Hydrolysis as a Function of pH	Hydrolytically unstable in the environmental pH range of 4-9.	Measured
Partition Coefficient (n-octanol/water)	A moderate log Pow is expected based on reported solubility in octanol of 1-10 g/L.	Estimated
Adsorption/Desorption	Expected to be surface active and absorb to organic matter and soils rich in organic carbon.	Estimated based on the chemical structure.
Dissociation Constant	Contains functionalities which are expected to have a pKa value of 3-5.	Estimated
Particle Size	Not determined	Will only be imported in diesel fuel.
Flash Point	Not determined	Will only be imported in diesel fuel.
Flammability	Not determined	Will only be imported in diesel fuel.
Autoignition Temperature	Not expected to autoignite under normal conditions of use.	Estimated
Explosive Properties	Not expected to be explosive	The structural formula contains no explosives.

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A.

The notified polymer has limited water solubility and expected to be slightly lipophilic and have a low vapour pressure. It is also expected to mainly exist in an ionised form over the environmental pH range (4-9).

Density

The notified polymer will only be imported as a component of diesel fuel. The specific gravity of the solvent solution containing ~50% of the notified polymer is 890 kg/m³.

Reactivity

The notified polymer is expected to be stable in diesel fuel.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer, a component of the fuel additive Dodiflow 5735, will be imported in ocean tankers as a component of diesel fuel at concentrations of < 100 ppm.

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

	<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
LTD/1374	<i>Tonnes</i>	< 12	< 12	< 12	< 12	< 12
Extension	<i>Tonnes</i>	< 120	< 120	< 120	< 120	< 120

PORT OF ENTRY

Western Australia (Geraldton, Dampier and Port Hedland)

Extension Applicant:

Esperance, Fremantle, Geraldton, Broome, Darwin, Cairns and Townsville.

TRANSPORTATION AND PACKAGING

Diesel fuel containing the notified polymer will be transported to townships from the ports by road in tanker trucks or by rail in rail cars.

USE

The notified polymer will be used as a cold flow improver for the petroleum industry.

OPERATION DESCRIPTION

Diesel fuel containing the notified polymer will be discharged in an enclosed system via transfer lines from the ship to a bulk terminal. Samples will be taken from the discharge lines by laboratory technicians for quality testing every hour during discharge of the fuel. Commonly the fuel will be discharged over a 10-hour period.

The fuel will then be transferred at the loading gantry to tanker trucks and rail cars using a fully automated and enclosed system. The fuel will then be taken by road to service stations, where it will be discharged via transfer lines by the truck driver, or by rail to be discharged into small tank farms at customer sites.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Tanker ship unloading	20	0	4
Sampling	1-2	0.5	4
Transport tanker truck loading	100	0	365
Transport tanker truck unloading	100	0	365
Rail car loading/unloading	30	0	52

EXPOSURE DETAILS

Minimal exposure is expected during transfer of the diesel fuel containing the notified polymer (< 100 ppm) from the ship until it reaches the customer sites as all transfers will be conducted in closed systems. However, dermal and ocular exposure may be possible during connection and disconnection of transfer lines, cleaning up spills and when taking samples for quality testing from the discharge line by laboratory technicians. In all cases where there is potential for exposure, workers are expected to wear gloves, goggles and coveralls as minimum personal protective equipment.

6.1.2. Public exposure

Dermal and ocular exposure to the notified polymer by the public may occur when filling vehicles with diesel fuel (< 100 ppm notified polymer).

6.2. Human health effects assessment

The results from toxicological investigations conducted on an acceptable analogue of the notified polymer are summarised in the table below. Details of this study can be found in Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rabbit, skin irritation (analogue)	Moderate to severely irritating

The result from the one toxicological endpoint given suggests that the notified polymer is moderately to severely irritating to the skin based on an acceptable analogue polymer. Given the lack of results for other toxicological endpoints, other hazards of the notified polymer may be possible.

Irritation.

An acceptable analogue of the notified polymer was determined to be moderate to severely irritating, based on the observation of moderate to severe erythema and slight oedema for all 3 rabbits tested for 3 days or more after application. These effects had resolved by 14 days. The analogue tested contains a large amount of residual monomers (> 30%) that are known skin irritants, and hence it is probable that the latter contribute strongly to the skin irritancy observed in the study. Given the presence of these residual monomers in both the analogue and notified polymer, it is not possible to determine their skin irritancy.

As the notified polymer contains similar residual monomers to the analogue, products containing the notified polymer may be classified as skin irritants.

In summary, the notified polymer has no confirmed hazards but it may be a possible irritant of unknown severity based on structural alerts (Hulzebos, 2005) and high concentration of low molecular weight species.

Health hazard classification

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). However, products containing the notified polymer may be classified as a skin irritant due to high percentage of residual monomers (classified as skin irritants) associated with the notified polymer.

6.3. Human health risk characterisation**6.3.1. Occupational health and safety**

Given the low concentrations (< 100 ppm) of the notified polymer in diesel fuel and the infrequency of exposure, the risk to workers from exposure to the notified polymer is not considered to be unacceptable.

6.3.2. Public health

Given the low concentrations (< 100 ppm) of the notified polymer in diesel fuel and the infrequency of exposure, the risk to the public from exposure to the notified polymer is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS**7.1. Environmental Exposure & Fate Assessment****7.1.1 Environmental Exposure****RELEASE OF CHEMICAL AT SITE**

The notified polymer will be imported as an additive of diesel fuel for direct use in Australia. No reformulation and subsequent releases of the notified polymer are expected in Australia.

RELEASE OF CHEMICAL FROM USE

The diesel fuel product containing the notified polymer will be stored and transported in tanks, and the fuel will be pumped through lines to smaller tanks for combustion in engines. Based on this use pattern, no significant releases of the notified polymer to the environment are expected, except as a result of accidental spills.

RELEASE OF CHEMICAL FROM DISPOSAL

Diesel fuel containing the notified polymer is unlikely to be disposed of in significant quantities. When disposal is necessary, for example, from a spillage or tank cleaning, liquid residues are expected to be sent for recycling or incinerated. Solid wastes such as tank sludge which may contain small quantities of notified polymer are likely to be disposed of to landfill.

7.1.2 Environmental fate

The notified polymer is used as an additive for diesel fuel, and the overwhelming proportion of the imported quantity of the notified polymer will share the fate of the fuel. Given the use pattern of the diesel fuel, this will involve combustion into water and oxides of carbon and nitrogen. Minor amounts of residues of the notified polymer may exist in fuel tanks, which may be washed for re-use, disposed of to landfill or incinerated for material recycling. The residual notified polymer may be either incinerated, or be disposed of to landfill with the tanks.

The notified polymer is not considered to be readily biodegradable based on the biodegradability study on an acceptable analogue polymer. However, this will not be a significant factor in the environmental fate of the notified polymer given the fact that no release to aquatic ecosystems will occur based on its reported use pattern.

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

7.1.3 Predicted Environmental Concentration (PEC)

The calculation of the PEC is not necessary given no release of the notified polymer to aquatic ecosystems is expected based on its use pattern.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on an acceptable analogue polymer are summarised in the table below. Details of the fish toxicity study on an acceptable analogue can be found in Appendix C.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LC50 35 mg/L	Harmful to Zebra fish
Bacteria Toxicity	EC50 17.9 mg/L*	May be harmful to microbial respiration*

*Based on an MSDS value for the same analogue.

7.2.1 Predicted No-Effect Concentration

Given no significant release of the notified polymer to the aquatic ecosystems is expected, the PNEC has not been derived to calculate the Risk Quotient (PEC/PNEC).

7.3. Environmental risk assessment

The major fraction of the imported quantity of the notified polymer is expected to be combusted in engines to yield oxides of carbon and nitrogen, and water. There are no pathways for significant release of the notified polymer into aquatic ecosystems based on the intended use as an additive in diesel fuels. As there are no pathways for significant environmental exposure, the risk of an adverse effect on the environment from the intended use of notified polymer is not expected to be unacceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. However, products containing the notified polymer may be classified as a skin irritant due to high percentage of residual monomers (classified as skin irritants) associated with the notified polymer.

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.

	<i>Hazard category</i>	<i>Hazard statement</i>
Environment	Acute Category 3	Harmful to aquatic life
	Chronic Category 3	Harmful to aquatic life with long lasting effects

Human health risk assessment

Under the conditions of the occupational settings described, 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

On the basis of the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Risk assessment (extension application)

The proposed use and fate of the notified polymer will not change under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environment risk assessment. Therefore there are no changes required in the risk assessment.

Recommendations

CONTROL MEASURES**Occupational Health and Safety**

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself as introduced, however, these should be selected on the basis of all ingredients in the formulation.

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 chemical 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.

Disposal

- The notified polymer should be disposed of by incineration or to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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 polymer is introduced in any other form other than a component of diesel fuel.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a cold flow improver for the petroleum industry, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 70 tonnes per annum, or is likely to increase, significantly;
 - 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.
Material Safety Data Sheet

The MSDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Water Solubility** < 1 g/L at 20°C

Method	OECD TG 105 Water Solubility.
Remarks	The solubility of the notified polymer in a variety of solvents including H ₂ O was estimated visually in a series of preliminary tests based on the shake-flask method. The notified polymer is not readily soluble in water.
Test Facility	Clariant (2007a)

Hydrolysis as a Function of pH Hydrolytically unstable at 25°C in the environmental pH range of 4 – 9.

Method	OECD TG 111 Hydrolysis as a Function of pH.
Remarks	<p>The degree of hydrolysis of the notified polymer at pH 4.0, 7.0 and 9.0 was measured as a function in the change in molecular weight.</p> <p>The hydrolysis of pendant functional groups in the notified polymer may lead to decreases in the molecular weight. As the molecular weight for the hydrolysable pendant side chains is less than the polymer molecular weight, it is considered that the actual percentage of hydrolysis would be higher than the measured percentage decrease in the polymer molecular weight.</p> <p>In the preliminary hydrolysis test, the changes in the molecular weight after 1 day at 50°C and pH 1.2, and 5 days at pH 4.0, 7.0 and 9.0 was about 40-50%. Hence, at least 10% of the notified polymer was hydrolysed during the test. Therefore, the notified polymer is not considered hydrolytically stable, and the hydrolysis half-life time could be estimated as < 1 year at 25°C.</p>
Test Facility	Clariant (2007b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Irritation – skin**

TEST SUBSTANCE	Acceptable analogue of notified chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	The substance was administered over the whole surface of a 2.5 x 2.5 cm cellulose patch on a piece of surgical plaster. The plaster was fixed to the prepared skin area and then covered with a semi-occlusive bandage. Due to persistent irritation at 72 hours after removal of the patches, additional readings were performed at 7 and 14 days.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	<i>Animal No.</i>					
	1	2	3			
<i>Erythema/Eschar</i>	3.0	3.0	2.67	3.0	7 days	0
<i>Oedema</i>	1.0	2.0	2.0	2.0	7 days	0

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

Remarks - Results For up to 7 days, the animals showed very slight to moderate or severe erythema. Very slight to slight oedema was observed up to 7 days in 2 animals, and up to 72 hours in one. At the 14-day observation, no irritation was observed. Additionally, the skin surface of the animals was dry, rough and fine scaled. Fine-scaled skin surface was still present at the end of the study.

CONCLUSION The notified polymer, based on its similarity to the analogue, is moderately to severely irritating to the skin.

TEST FACILITY Aventis Pharma (2000)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS**C.1. Environmental Fate****C.1.1. Ready biodegradability**

TEST SUBSTANCE	Acceptable analogue of notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Inoculum	Non adapted activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Titrimetric analyses of the quantity of evolved CO ₂ .
Remarks - Method	The degradation was expressed as percentage ThCO ₂ (i.e. theoretically produced CO ₂ based on carbon composition) and was calculated for each titration of CO ₂ .
	The test substance was tested at a concentration of 15 mg/L in duplicates, corresponding to a carbon content (TOC) of 12.4 mg/L.
	In order to check the activity of the test system, sodium acetate was used in the functional control test at a concentration of 35 mg/L, corresponding to a carbon content (TOC) of 10.2 mg/L.

RESULTS

<i>Acceptable analogue</i>		<i>Sodium Acetate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
6	1	6	33
14	0	14	63
21	0	21	60
28	0	28	56

Remarks - Results	<p>The percentage degradation of the reference substance reached the pass level of > 60% after 11 days, and a degradation of 63% was reached within 14 days. The activity criterion of the guideline is fulfilled.</p> <p>A maximum biodegradation rate of 36% occurred within 14 days in the toxicity control test. This suggests that the test substance was not inhibitory to the biodegradation of the reference substance.</p> <p>The biodegradation of the test substance remained at a level of 0 – 3%.</p>
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CONCLUSION	The analogue polymer is not considered to be readily biodegradable based on the results of this test. The notified polymer is not considered to be readily biodegradable given its structural similarity to the analogue.
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TEST FACILITY	Dr. U. Noack-Laboratorium (2001).
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C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Acceptable analogue of notified polymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test- Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static.
Species	<i>Brachydanio rerio</i> (Zebra fish)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	67 mg CaCO ₃ /L
Analytical Monitoring	Total Organic Carbon (TOC) and Dissolved Organic Carbon (DOC).
Remarks – Method	Tap water of local origin was used as the test medium after being filtered on activated charcoal and aerated for at least 24 hours to remove chlorine.

A preliminary study was conducted at a nominal concentration of 100 mg/L with 7 fish. A mortality of 29% was observed after 24 hours in this test.

Test concentrations in the range of 25 – 200 mg/L showed turbidity through out the definitive test.

The LC50 values were calculated by probit analysis.

RESULTS

Nominal Concentration (mg/L)	Number of Fish	Mortality				
		2 h	24 h	48 h	72 h	96 h
200	7×2	14	14	14	14	14
100	7×2	14	14	14	14	14
50	7×2	14	14	14	14	14
25	7×2	0	0	0	0	0
12.5	7×2	0	0	0	0	0

LC50	35 (95% C.I.: 33 – 38) mg/L at 96 hours.
NOEC	25 mg/L at 96 hours.
Remarks – Results	No mortality or non-lethal effects were observed in the definitive test at concentrations up to 25 mg/L and in the control test.

CONCLUSION	The analogue polymer is considered harmful to fish. The notified polymer is considered harmful to fish based on its structural similarity to the analogue.
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TEST FACILITY	Dr. U. Noack-Laboratorium (2000).
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