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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

X-16349

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 Sustainability, Environment, Water, Population and Communities.

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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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FULL PUBLIC REPORT

This notification has been carried out under the approved foreign scheme provisions (Canada) of Section 44 of the Act. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

X-16349

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Afton Chemical Asia Pacific LLC (ABN: 99 109 644 288)
Level 9, 20 Berry Street
North Sydney, NSW 2059

BP Australia Pty Ltd (ABN: 53 004 085 616)
717 Bourke Street
Docklands, VIC 3008

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, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: vapour pressure, hydrolysis as a function of pH, partition coefficient, dissociation constant and explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2010), U.S.A (2009)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
X-16349

MOLECULAR WEIGHT
Mn >1000 Da

ANALYTICAL DATA
Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY >80%

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Boiling Point	Decomposes without boiling at	Measured

	>295	
Density	850 kg/m^3 at 20 ^{o}C	Measured
Vapour Pressure	Not determined	Based on the high molecular weight, vapour pressure is expected to be low.
Water extractability	≤0.31%	Measured according to OECD TG 120
Hydrolysis as a Function of pH	Not determined	Not required since the water extractability was determined to be <2%
Partition Coefficient (n-octanol/water)	Not determined	Not required since OECD TG 117 is not considered suitable for the notified polymer due to its surface active properties. EPI v4.0 and the notifier calculated a log K_{OW} of >6.
Adsorption/Desorption	Not determined	EPI v4.0 and the applicant (using a QSAR) calculated a log K_{OC} of >5.63 (see below for discussion).
Dissociation Constant	pK_{a1} = 5.31 pK_{a2} = 5.24	Predicted using Pallas v3.7.1.1. The notified polymer is expected to be ionised in the environmental pH range of 4 – 9.
Flash Point	230 ^{o}C	Measured
Flammability	Not highly flammable	Measured
Autoignition Temperature	453 ^{o}C	Measured
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.

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

Based on the water extractability data, only negligible amounts of the substance are expected to stay in the water column if it is released into the water. However, considering its surface active nature, the notified polymer may partition between the water phase and organic carbon in sediments despite the calculated high log K_{OC}.

Reactivity
The notified polymer is expected to be stable under normal conditions of use. Decomposition will occur at elevated temperatures.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported as a component of a fuel additive at <5% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤30	≤30	≤30	≤30	≤30

PORT OF ENTRY
Sydney, Melbourne, Brisbane and Perth

IDENTITY OF MANUFACTURER/RECIPIENTS
Afton Chemical Asia Pacific LLC and BP Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The additive containing the notified polymer (at <5% concentration) will be imported in 205 L steel drums or isotanks. The additive and fuel will be distributed by road to end-users.

USE
The notified polymer will be used as an additive for diesel fuel (at <0.05%) for cars, locomotives and marine, mining, agricultural and heavy-duty on-road equipment.

OPERATION DESCRIPTION
Upon delivery of the imported product (<5% notified polymer) to blending facilities, it will be pumped into storage tanks. It will then be transferred to the blending vessel by automated means. Following blending, the diesel fuel containing the notified polymer (at <0.05%) will be distributed to refuelling facilities, where it will be used by workers or the public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Analysis of additive package	1	0.5	12
Unloading isotanks and drums	1-2	0.5	12
Sampling and analysing finished fuel	1	0.5	12
Filling containers with finished fuel	1-2	4	12
Maintenance workers	1-2	4	4
End-users	unspecified	4	220

EXPOSURE DETAILS
The potential routes of exposure to the polymer are dermal and ocular. Inhalation exposure is not expected as the polymer is expected to have a low vapour pressure, and the generation of aerosols is not expected.

Transport and storage workers may come into contact with the imported product or diesel fuel (<5% notified polymer) only in the event of accidental rupture of containers.

At blending facilities, operations will be largely automated and conducted in a closed system. Exposure to the notified polymer in the additive (at <5%) or in the diesel fuel (<0.05%) may occur during connection/disconnection of hoses, during quality assurance and during maintenance tasks. Exposure will be minimised by the use of personal protective equipment (PPE), including chemical goggles, impervious gloves and appropriate industrial clothing. During end-use, dermal or ocular exposure to the fuel containing the notified polymer at <0.05% is possible during the connection and disconnection of transfer hoses and/or during the fueling of vehicles. PPE is unlikely to be worn during such processes.

6.1.2. Public Exposure
The public may be exposed to the notified polymer at <0.05% through operations such as refuelling vehicles.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the following table.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2,000 mg/kg bw; low toxicity

	Study was performed on female rats (3/group) using the acute toxic class method (administered by oral gavage to two groups at 2000 mg/kg bw). There were no mortalities or signs of systemic toxicity in the animals. Hunched posture and/or piloerection were noted in all animals on Day 1.

Based on the high molecular weight (>1000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure is limited. However, the polymer contains an appreciable proportion of low molecular weight species (<1000 Da) that may be absorbed.

The notified polymer contains a functional group, which is a structural alert for carcinogenicity, reproductive toxicity and irritation. The potential for some of these effects may be reduced due to the high molecular weight (and high partition co-efficient/low water solubility) of the notified polymer. However, due to the presence of an appreciable proportion of low molecular weight species, these effects cannot be ruled out.

Health hazard classification
Based on the limited toxicity data provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer will be handled by workers at <5% concentration as imported, and at <0.05% in end-use products. At such concentrations, irritant and/or reproductive toxicity effects following exposure are not expected. However, the carcinogenic potential associated with exposure to the notified polymer cannot be ruled out. Therefore, care should be taken to avoid direct contact with the notified polymer.

Provided that control measures are in place to minimise worker exposure, including the use of automated processes and the wearing of PPE when handling the imported product, the risk to the health of workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The public may be incidentally exposed to the notified polymer at <0.05% through operations such as refuelling vehicles. Based on the low concentration of the polymer in the fuel and the expected low exposure of the public to the fuel during vehicle refilling, the risk to the public from use of diesel fuel containing the notified polymer at <0.05% is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported in marine isotanks or 205 L steel drums as an additive for diesel fuel for marine, mining, agricultural and heavy-duty on-road equipment. Immediately following import, the isotanks or drums will be transported by road or rail to lubricating oil and diesel fuel manufacturers. No significant release of the polymer is expected from the processes of manufacturing and transportation.

Blending of the additive containing the notified polymer into diesel fuels is expected to occur in well-controlled industrial facilities. The container filling processes are computer automated, so minimal spills due to loading are expected. Losses from spills and leaks in the filling/packaging process may be up to 5 g of the notified polymer.

RELEASE OF CHEMICAL FROM USE
The fuels containing the notified polymer are expected to be available at commercial fuel outlets for use in mining, marine, agricultural and heavy-duty on-road applications. The notified polymer is consumed during the combustion of the fuel to generate primarily water and oxides of carbon and nitrogen.

RELEASE OF CHEMICAL FROM DISPOSAL

Isotanks and drums are anticipated to be sent for cleaning and reconditioning by a licensed company. The resultant washings from such companies are typically passed to an on-site waste treatment facility and any waste sludge is likely to be sent to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer does not contain any functional groups that would be susceptible to biodegradation, and therefore is not considered to be readily biodegradable. Given the molecular weight (Mn >1000 Da) and low oligomer content, the notified polymer is unlikely to cross biological membranes, and therefore, it would not be considered to be bioaccumulative.

Most of the notified polymer in diesel fuel will be consumed and degraded during use. Minor amounts of the notified polymer are expected to be released to landfill as residues in containers or treatment wastes. The notified polymer is expected to degrade by slow biotic and abiotic processes in landfill, or by thermal decomposition, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The PEC has not been calculated since no significant release of the notified polymer to the water environment is expected from the reported use pattern.

7.2. Environmental Effects Assessment

The results of ecotoxicological testing on the notified polymer showed the absence of adverse effects to fathead minnow (*Pimephales promelas*), daphnia (*Daphnia magna*) and green algae (*Pseudokirchneriella subcapitata*). Due to the low water solubility of the notified polymer, nominal water accommodated fractions (WAF) of 100 mg/L were used as loading rates.

One other acute ecotoxicity test reported immobile and lethargic daphnids in the 6.3 mg/L treatment group whereas this effect was not considered to be related to the treatment with the test substance, due to the absence of effects in the next three higher concentrations treatment groups (13 mg/L, 25 mg/L and 50 mg/L). Therefore, the no-immobility level and the NOEL were both 50 mg/L and the EC50 for 24 hour and 48 hour were estimated to be >100 mg/L (>80 mg/L corrected for pure active ingredient), the highest concentration tested.

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below.

Study	*EL [mg/L]*	*EL_{corr}* [mg/L]*	*Test method*	*Assessment Conclusion*
Fish Toxicity	96 h LL50 >100 (WAF)	> 80	OECD TG 203	Not harmful to fish
Daphnia Toxicity	48 h EL50 >100 (WAF)	> 80	OECD TG 202	Not harmful to daphnia
Algal Toxicity	96 h EL50 >100 (WAF)	> 80	OECD TG 201	Not harmful to algae

* Corrected for 100% active ingredient

On the basis of these results, the notified polymer is not considered to be harmful to aquatic species up to the limit of its water solubility.

7.2.1. Predicted No-Effect Concentration

Given the low water solubility and low potential for release of the notified polymer to the aquatic environment, the calculation of the PNEC is not considered necessary.

7.3. Environmental Risk Assessment

Calculation of the Risk Quotient Table (PEC/PNEC) is not possible since neither the PEC nor the PNEC is available. The notified polymer is not considered to pose an unreasonable risk to the aquatic environment based on its lack of ecotoxicity to aquatic species and assessed use pattern indicating low potential for release to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited toxicity data provided, the notified polymer cannot be classified according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations
CONTROL MEASURES
Material Safety Data Sheet

- The MSDS for the notified polymer (as introduced) should reflect the concerns regarding potential carcinogenicity.

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer, as introduced:
  - Automated processes, where possible

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer, as introduced:
  - Avoid direct contact

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

  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.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- 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;
- the concentration of the polymer in diesel fuel is >0.05%.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from an additive in diesel fuel, or is likely to change significantly;
- the amount of polymer being introduced has increased from 30 tonnes per annum, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet
The MSDS of 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

Boiling Point Decomposes without boiling at >295 ºC

Method	Internal Test Method
Remarks	Determined by Differential Scanning Calorimetry (DSC). Full test report not provided. The notified polymer exhibited a slight endotherm at 296.3 ºC, indicating some volatilisation of the sample, immediately prior to the onset of decomposition.
Test Facility	Afton (2011a)

Density 850 kg/m^3 at 20 ºC

Method	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using pycnometer method (using a Class A graduated tube).
Test Facility	SRI (2011a)

Flash Point 230 ºC

Method	ASTM D93, Standard Test Method for Flash Point by Pensky-Martens Closed Cup Tester
Remarks	Determined using an automatic closed cup flash point analyser.
Test Facility	Afton (2011b)

Flammability Not highly flammable

Method	EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks	A hot flame from a gas torch was applied to one end of a 200 x 10 x 250 mm strip on a glass plate. Sustained flames remained above the melted segment and did not propagate along the strip. The flames self-extinguished following torch withdrawal.
Test Facility	SRI (2011b)

Autoignition Temperature 453 ± 3 ºC

Method	ASTM E659-78, Standard Test Method for Autoignition Temperature of Liquid Chemicals
Remarks	None
Test Facility	SRI (2011c)

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