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

PUBLIC REPORT

Polymer in HiTEC4546 and AvGuard SDA

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1900	Afton Chemical Asia Pacific LLC	Polymer in HiTEC4546 and AvGuard SDA	ND*	< 8 tonnes per annum	Diesel and gasoline fuel additive

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 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 reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in fuel add-packs:
 - Avoid direct skin/eye contact with the product
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in fuel add-packs:
 - Protective clothing
 - Safety glasses
 - Impervious gloves
- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself; however, these should be selected on the basis of all ingredients in the formulation, noting that the formulation may be classified as R37/38 because of hazardous impurities.

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

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from diesel and gasoline fuel additive or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

(Material) Safety Data Sheet

The (M)SDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

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

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Afton Chemical Asia Pacific LLC (ABN: 99 109 644 288)
Level 9, 20 Berry Street
NORTH SYDNEY NSW 2059

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ 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, manufacture/import volume, site of manufacture/reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a function of pH, Adsorption/Desorption Coefficient, Flash Point and Dissociation Constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (2012), Canada (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

HiTEC4546 and AvGuard SDA (containing notified polymer at < 15%)

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 30%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

None under normal conditions of use.

DEGRADATION PRODUCTS

No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Liquid (Product containing the notified polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	37.2 °C	Provided by the notifier (Measured)
Density	926.3 kg/m ³ at 15.6 °C	Provided by the notifier (Measured)
Vapour Pressure	2.4 × 10 ⁻⁵ kPa at 25 °C	Measured
Water Solubility	< 1 × 10 ⁻³ g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined.	Notified polymer does not contain hydrolysable functionalities.
Partition Coefficient (n-octanol/water)	log Pow > 6.5 at 20 °C	Measured
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sludge due to its expected low water solubility, high molecular weight and the presence of the potentially cationic functionalities.
Dissociation Constant	Not determined	The notified polymer contains potentially cationic functionalities with a typical pKa ~ 10. It is expected to be ionised in the environmental pH range (4 - 9).
Particle Size	Not determined	The notified polymer is not isolated from liquid form.
Flash Point	150 °C	(M)SDS of a product containing the notified polymer.
Autoignition Temperature	Not determined	Expected to be high based on the flash point.
Explosive Properties	Not determined	Contains no chemical groups associated with explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

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

Reactivity

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

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a component of a formulated product at concentrations < 15%.

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

Year	1	2	3	4	5
Tonnes	5-8	5-8	5-8	5-8	5-8

PORT OF ENTRY

Sydney, Melbourne, Brisbane and Perth

IDENTITY OF MANUFACTURER/RECIPIENTS

Major diesel and gasoline fuel manufacturers.

TRANSPORTATION AND PACKAGING

The notified polymer will be imported into Australia as a component of add-packs in 45 US gallon steel drums by ship, and then transported by road or rail.

Blended fuel containing the notified polymer at < 0.0002% concentration will be transported by bulk tank trucks (20,000 kg/load) to retail fuel establishments and stored in underground storage tanks.

USE

The notified polymer will be used as an additive at < 0.0002% concentration in diesel and gasoline fuels. It will assist in the dissipation of static electricity during bulk transfer operations.

OPERATION DESCRIPTION

At industrial fuel-blending sites, the fuel add-packs containing the notified polymer (< 15% concentration) will be transferred from local storage tanks to the blending vessel through dedicated pipes in a typically automated and enclosed system. Quality control sampling may occur immediately after blending. Blended fuel containing the notified polymer at < 0.0002% concentration will be transferred through dedicated pipes to bulk storage tanks and then to 20,000 kg bulk tank trucks for transport to commercial and retail fuel outlets.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
QC/QA analysis of additive product upon receipt	< 45 minutes	< 1 day/year*
Blending from additive drums into fuel	~30 minutes	30-45 days/year
Sampling of fuel after blending	~30 minutes	30-45 days/year
Filling containers with fuel (transport and delivery)	~6-8 hrs	100-150 days/year
Maintenance/Inspection personnel	~4-6 hrs	30-45 days/year
Commercial fuel users (diesel and gasoline)	~4-6 hrs	260-365 days/year

*Mainly performed by the notifier

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are not expected to be exposed to the imported product containing the notified polymer at < 15% concentration, as they will be handling closed containers. Dermal or ocular exposure is possible in the event of an accident where the packaging is breached or during transfer to storage tanks. Worker exposure will be minimised by the use of overalls, safety boots and gloves.

Blending

During the blending process, the worker exposure is expected to be minimal as this will occur in an enclosed and automated system. Incidental dermal and ocular exposure to the imported fuel add-packs containing the notified polymer at < 15% may occur, during the connection and disconnection of the lines used to charge the blending vessels, and during maintenance activities. However, workers are expected to wear personal protective equipment such as gloves, eye protection, protective clothing, and hard hats. Following blending, the final product containing the notified polymer at a concentration of < 0.0002% will be transferred to storage tanks through an enclosed and automated process with minimal worker exposure expected. Maintenance workers involved in cleaning, blending and filling equipment may be exposed to residues containing the notified polymer at a concentration of < 0.0002%.

Laboratory Staff

Dermal exposure of laboratory staff during sampling and testing is expected. The exposure would be minimal due to the brief sampling periods and the small quantities involved and would be further reduced by the expected use of PPE such as gloves, lab coats and safety glasses.

End Users

End users of the finished product may be exposed to the notified polymer at a concentration of < 0.0002% during car and vehicle filling, handling automotive components and during cleaning of equipment.

6.1.2. Public Exposure

The add-packs containing the notified polymer will not be made available to the general public. The public may experience accidental dermal and ocular exposure to fuels containing the notified polymer at < 0.0002% concentration when re-filling vehicles at service stations.

6.2. Human Health Effects Assessment

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

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity

Toxicokinetics, metabolism and distribution.

No data on toxicokinetics for the notified polymer was provided. For dermal absorption, molecular weights below 100 Da. are favourable for absorption and molecular weights above 500 Da do not favour absorption (ECHA, 2014). In substances with log P values above 6, the rate of transfer between the stratum corneum and the epidermis will be slow and will limit absorption across the skin (ECHA, 2014). The notified polymer is of high molecular weight (> 1,000 Da), and partition coefficient (log Pow > 6.5 at 20 °C) and low water solubility (< 1 × 10⁻³ g/L at 20 °C). Therefore absorption across biological membranes is expected to be low.

Acute toxicity.

The notified polymer is of low acute toxicity via the oral route.

Irritation and sensitisation.

No irritation studies were provided. However, the notified polymer contains a structural alert for corrosion/irritation.

Health hazard classification

Based on the available information, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The toxicological properties of the notified polymer have not been fully investigated. A structural alert in the notified polymer for corrosion/irritation has been identified. Systemic toxicity is not expected based on the low potential for absorption and the lack of toxicity seen in the acute oral study.

Dermal and ocular exposure will be the main routes of worker exposure to the notified polymer in fuel add-packs containing the notified polymer at < 15% concentration and in finished fuel containing < 0.0002% notified polymer. Worker exposure is expected to be reduced by various control measures and safe work practices, including engineering controls and PPE.

Based on the available information on toxicity and the expected low exposure of workers to the notified polymer, it is not expected to pose an unreasonable risk to workers.

6.3.2. Public Health

The public may be incidentally exposed to the notified polymer in diesel fuel at < 0.0002% through operations such as refuelling vehicles. Due to the low concentration of the notified polymer in the diesel fuel and the expected low hazard of the notified polymer, the risk to the public 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 not be manufactured in Australia and will be imported as a component of an additive that will be blended into diesel and gasoline fuels. Significant release of the notified polymer to the environment is not expected during transport and storage except in the unlikely event of accidental spills or leaks. Blending will take place in fully enclosed automated systems. Spills and leaks during blending are expected to be minimal through the use of engineering controls and industry specific procedures. Any spills incurred in the blending operations will be contained within concrete bunds and either reclaimed or disposed of in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

When used as a fuel additive, the notified polymer is expected to be blended into fuels in well-controlled industrial facilities. Once blended, these fuels are expected to be available for use by large mining companies, trucking companies, and fuel retailers. The majority of the notified polymer is expected to be thermally decomposed during use as fuel additive and its decomposition products released to the atmosphere. The notified polymer is not significantly water soluble and it is not expected to be volatile. It will tend to remain part of the fuel into which it is blended. These combined factors will result in no significant exposure to the environment.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty containers containing the residue of the notified polymer are expected to be recycled by accredited waste management companies or disposed of according to local regulations. Any sludge remaining in the empty containers are expected to be managed as hazardous solid waste and disposed of according to local regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer will be thermally decomposed during use and is expected to form water and oxides of carbon and nitrogen. The notified polymer is not likely to be readily biodegradable. It is also expected to have limited release to the aquatic environment based on the assessed use pattern. Notified polymer released to soil through leaks and spills, or released to landfill as residues in empty containers, is expected to associate strongly with organic matter. It is expected to remain *in situ* based on its low water solubility, and potential high affinity for organic phases with an expected high n-octanol/water partition coefficient ($\log P_{ow} > 6.5$) and likely high adsorption/desorption coefficient. The notified polymer is expected to degrade via biotic and abiotic processes to form simple organic compounds, water and oxides of carbon and nitrogen.

The notified polymer may be persistent based on its low water solubility and high n-octanol/water partition coefficient (P_{ow}). However, based on its high molecular weight, combined with limited aquatic exposure, suggests that it has a low potential for bioaccumulation.

7.1.3. Predicted Environmental Concentration (PEC)

Exposure to the aquatic compartment is not expected during the use and disposal of the notified polymer. Therefore calculation of a predicted environmental concentration (PEC) is not considered necessary.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer using a water accommodated fraction (WAF) are summarised in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	96 h LL50 > 100 mg/L (WAF)	Not harmful to fish
Daphnia Toxicity	48 h EL50 = 42 mg/L (WAF)	Not harmful to aquatic invertebrates up to its limit of solubility
Algal Toxicity	72 h ErC50 = 4 mg/L (WAF)	Not harmful to algae up to its limit of solubility

The notified polymer is not expected to be acutely harmful to aquatic invertebrates up to the limits of its water solubility. Therefore, the notified polymer is not formally classified for acute or long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

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

The notified polymer is expected to have limited release to the aquatic environment based on its assessed use as a fuel additive in diesel and gasoline industry. The notified polymer has the potential to persist in the aquatic compartments however it has low toxicity to aquatic organisms and is not expected to bioaccumulate based on its high molecular weight and low water solubility. On the basis of the limited aquatic exposure, the notified polymer is not expected to pose an unreasonable risk to the environment for the assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Melting Point/Freezing Point** 37.2 °C

Method	ASTM D-127 Method
Remarks	Melting point
Test Facility	Saybolt Petroleum Services (2015)

Density 926.3 kg/m³ at 15.6 °C

Method	Not specified
Test Facility	Afton Chemical (2015)

Vapour Pressure 2.4 × 10⁻⁵ kPa at 25°C

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Balance method
Test Facility	Harlan Laboratories Ltd (2012a)

Water Solubility < 1×10⁻³ g/L at 20 °C

Method	OECD TG 120 Solution/Extraction Behaviour of Polymers in Water.
Remarks	Gel Permeation Chromatography (GPC)
Test Facility	Harlan Laboratories Ltd (2012b)

Partition Coefficient (n-octanol/water) log Pow > 6.5 at 20 °C

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	HPLC Method
Test Facility	Harlan Laboratories Ltd (2012b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	The notified polymer		
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.		
Species/Strain	Rat/Wistar		
Vehicle	Arachis oil BP		
Remarks - Method	A group of three fasted female rats was treated with the test item at 300 mg/kg bw. Then two other groups of three fasted female rats were treated at 2,000 mg/kg bw.		
RESULTS			
<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
A	3F	300	0/3
B	3F	2000	0/3
C	3F	2000	0/3
LD50	> 2,000 mg/kg bw		
Signs of Toxicity	There were no signs of systemic toxicity.		
Effects in Organs	All animals showed expected gains in body weight over the study period.		
Remarks - Results	Epithelial sloughing of the gastric mucosa was noted at necropsy of 3/6 animals treated at 2,000 mg/kg bw.		
CONCLUSION	The notified polymer is of low toxicity via the oral route.		
TEST FACILITY	Harlan Laboratories Ltd (2012c)		

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