File No EX/164
(PLC/890)

August 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)

FULL PUBLIC REPORT

Polymer in SAG TP-325

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, AUSTRALIA.

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 assessment report is for an extension of original assessment certificate for Polymer in SAG TP-325. 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.

Polymer in SAG TP-325

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Holders of the Original Assessment Certificate (PLC/890):
Momentive Performance Materials Australia Pty Ltd (ABN 47 105 651 063)
Level 2, 600 Victoria Street
RICHMOND VIC 3121

A.S. Harrison & Co Pty Ltd (ABN 89 000 030 437)
75 Old Pittwater Road
BROOKVALE NSW 2100

Applicant for an Extension of the Original Assessment Certificate:
Connell Bros Company Australasia Pty Ltd (ABN 53 079 159 327)
3/32 Windorah Street
STAFFORD, QLD 4053

NOTIFICATION CATEGORY
Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, Marketing Name, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities and Import Volume.

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
USA (1994)
Korea (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SAG TP-325
SAG TP-367
Y-14970
Y-14928

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 10,000 Da

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Viscous, colourless, translucent liquid
Melting Point/Glass Transition Temp	< 0°C
Density	1040 kg/m^3 at 25°C (Note: units are kg/m^3; density in kg/m^3 is 1000 x density in g/cm^3)
Water Solubility	< 4 × 10^{-4} g/L at 20°C for SAG TP-325. The formulated product was observed to form a white solid immediately on contact with water. The notified polymer is amphiphilic and may be dispersible in water to a limited extent.
Partition Coefficient	log P_{OW} > 7.5 for SAG TP-325, estimated by determining the solubility of the product in pure solvents.
Particle Size	Liquid at room temperature
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 10	< 10	< 10	< 10	< 10

Extension application

Year	1	2	3	4	5
Tonnes	< 10	< 10	< 10	< 10	< 10

Use
The notified polymer will be used as an additive in diesel fuels and lubricants.

Mode of Introduction
The notified polymer will be imported initially as a component of a diesel fuel additive package at < 1.0%. At some future time, the notified polymer will be imported as a component of diesel fuel packages and lubricant products: SAG TP-325 (containing < 50% notified polymer), SAG TP-367 (containing < 50% notified polymer), Y-14928 (containing < 70% notified polymer) and Y-14970 (containing < 90% notified polymer).

It is expected that imports will be by sea into all major ports in 205 L steel drums. After some years, import may be in IBCs or ISO containers.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the product SAG TP-325 containing the notified polymer at < 50% (refer to table below).

Endpoint	*Result*	*Effects Observed?*	
1. Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD TG 401
2. Rat, acute dermal	LD50 > 2000 mg/kg bw	yes	OECD TG 402
3. Rabbit, skin irritation	slightly irritating	yes	OECD TG 404
4. Rabbit, eye irritation	slightly irritating	yes	OECD TG 405
5. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

Acute dermal
The test article did not induce any erythema or oedema. Desquamation was observed for eight animals sporadically during the study. There were no other dermal findings.

Skin irritation
Very slight and slight erythema was noted for two and one animals, respectively. There was no oedema. Desquamation was noted for one animal. All dermal irritation was completely resolved by study termination (Day 14). There were no other dermal findings.

Eye irritation
Slight conjunctival irritation was observed in all 3 animals tested. There were no other ocular findings. The conjunctival irritation was resolved within 72 hours for two animals but persisted through to study Day 14 for one animal.

Given that the tested substance only contains < 50% of the notified polymer, it is not certain if the effects observed were as a result of the notified polymer. However, the irritation effects observed are not severe enough for classification of the polymer as a hazardous substance according to the *Approved Criteria for Classifying Hazardous substances [NOHSC: 1008(2004)]*.

Occupational Health and Safety Risk Assessment
Based on irritation studies conducted on the product SAG TP-325 (containing the notified polymer at < 50%), the notified polymer may have some potential for slight skin and eye irritation. The risk of irritation is not expected when handling the diesel fuel additive package or lubricant product that only contains the notified polymer at low concentrations (< 1%). However, there is a risk of some irritation potential when handling the products SAP TP-325, SAG TP-367, Y-14928 and Y-14970 that contain the notified polymer at < 50%, < 50%, < 70% and < 90% respectively. The expected use of PPE (safety goggles, coveralls and impervious gloves) by workers when handling these products should reduce the risk of irritation.

Overall, the OHS risk presented by the notified polymer is not considered unreasonable, based on the proposed use of PPE when handling the notified polymer at high concentrations in products, and the assumed low hazard of the notified polymer.

Public Health Risk Assessment
The public will be exposed to the notified polymer (at ~ 2.5 ppm) when filling vehicles with diesel fuel or at ≤ 200 ppm when filling vehicles with lubricant products containing the notified polymer. Given the low concentration and assumed low hazard, the risk to public health from exposure to the notified polymer is considered to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation
The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by an environmental endpoint observed in testing conducted on the product SAG TP-325 (containing the notified polymer at < 50%):

Endpoint	*Result*	*Effects Observed?*	
Fish Toxicity	LC50 > 200 mg/L nominal	Yes	TSCA Guideline 797.1400 (Flow Through)

Based on the results of the above study, the 96 hour LC50 value for the notified polymer (present in SAG TP-325) and fathead minnow was empirically estimated to be > 200 mg notified polymer/L, the highest nominal concentration tested. The NOEC established for this study was 200 mg notified polymer/L. The presence of undissolved test material in the toxicant delivery system indicated that the concentration range maintained during this study exceeded the test material's limit of water solubility. Due to the limited water solubility of the test material under maintained test conditions, further testing at higher concentrations to establish an LC50 was not considered practical. According to GHS, the notified polymer may be classified as being not harmful to fish up to the limit of its solubility in water.

Environmental Risk Assessment
The notified polymer will initially be imported as a component of a diesel fuel or lubricant additive for use in Australia. The notified polymer will be blended into finished diesel and lubricant products using semi-closed or closed systems, minimising the potential for environmental release due to spills, etc.

At some future time, the notified polymer will be imported into Australia at concentrations up to 90% that will undergo reformulation into diesel fuels or lubricants. Reformulation is expected to occur using semi-closed or closed systems that should minimise the potential for environmental release.

The diesel fuel blended with the fuel additive 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 such as power plants and trucks. Based on this use pattern, no significant releases of the notified polymer to the environment are expected, except as a result of accidental spills.

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 be thermally decomposed to recover their calorific value. Solid wastes such as tank sludge which may contain small quantities of notified polymer are likely to be disposed of to landfill.

As the notified polymer is used as an additive for diesel fuel, a large 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 silicon. Minor amounts of residues of the notified polymer may exist in the import containers, which may be washed for reuse, disposed of to landfill or incinerated during metal recovery operations. The residual notified polymer will share the fate of the import container.

Lubricant products containing the notified polymer will be distributed to industrial sites and retail outlets before being added to vehicle engines. At the end of the product life, lubricants containing the notified polymer are expected to be recycled or disposed of to landfill and significant releases to the environment are not expected, except as a result of accidental spills.

The notified polymer is not considered to be readily biodegradable based on a submitted biodegradability study for the product SAG TP-325, which reported 1.3% degradation after 5 days (based on chemical oxygen demand calculations), using the methods of OECD TG 301D (Closed Bottle Test). However, this will not be a significant factor in the environment fate of the notified polymer given the fact that no release to aquatic ecosystems will occur based on its reported use pattern.

The major fraction of the imported quantity of the notified polymer is expected to be combusted in engines to yield oxides of carbon, silicon, and water, recycled or disposed of to landfill. 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 and lubricant products. The notified polymer is also unlikely to be released to the air compartment as the vapour pressure will be very low. 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 acceptably low.

8. RISK ASSESSMENT AND RECOMMENDATIONS RELATING TO EXTENSION APPLICATION

The proposed use, introduction volume and fate of the notified polymer will not change significantly under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environmental risk assessment and recommendations.

9. CONCLUSIONS AND RECOMMENDATIONS

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
Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer when introduced in products at high concentrations (> 50%):
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer when introduced in products at higher concentrations (> 50%):
  - Safety goggles
  - Coveralls
  - Impervious gloves

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

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

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

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills and/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 polymer 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 polymer, 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from a component of a lubricant or a diesel fuel additive package, or is likely to change significantly;
  - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
  - the notified polymer 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 imported products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Extension Application:
The extension applicant has provided an MSDS for a product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.