File No PLC/545

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Viscoplex® 12/6322

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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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Degussa Australia Pty Ltd (ABN 80 005 415 752)
30 Commercial Drive
DANDENONG VIC 3175

NOTIFICATION CATEGORY
Polymer of Low Concern

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, Use Details, Manufacture/Import Volume, and Site of Manufacture/Reformulation

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
Korea (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
VISCOPLEX® 12-151 (0001)
VISCOPLEX® 12-151 (4001)
PA-8358

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10000

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
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

4. 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 lubricating oil. The notified polymer will be imported in 175 kg drums via ship or aeroplane and distributed via road to various reformulation sites where it will be formulated into driveline oils.

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

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

USE
Additive in driveline oils.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The imported lubricating oil containing <80% notified polymer will be transported by road to the notifier's storage facilities or the storage facilities owned by customers of the notifier. No repacking of lubricating oil will occur at the notifier's storage facilities.

At the reformulation site a sealed delivery system will be employed to transfer the lubricating oil containing the notified polymer from the shipment containers to blending vessels for mixing with other driveline oil ingredients. The resulting driveline oil product containing <40 % notified polymer will then be filled into bulk containers, drums, 4 litre jugs, or 1 litre bottles and transported to distributors and/or a range of end-users such as automotive manufacturers plants, commercial sites or consumer markets across Australia.

At the automotive manufacture plants, the driveline oil is transferred from bulk containers to storage tanks using sealed delivery systems. Metered amounts of the driveline oils are dispensed into vehicle gearbox on the assembly line via a sealed deliver system by trained personnel.

At commercial garages, the workers will change driveline oil in their customer's vehicles. The driveline oil is pumped using sealed delivery. The driveline oil containing the notified polymer will also used by consumers who change the driveline oil in their own vehicles.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

Dermal and ocular exposure can occur during certain formulation processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

6.2. Summary of Public Exposure

The driveline oil containing the notified polymer is for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer, when changing the gearbox oil.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

Since the notified polymer will not be manufactured locally, there will be no environmental exposure associated with this process in Australia. The losses during transportation, storage and handling and during the blending process and use in industrial assembly plants are minimised by the safety practices,

use of sealed delivery systems and automated and computer controlled processes.

Each year, about 581 million litres of lubricating oil is sold in Australia, and about 303 million litres of waste oil is generated. The remainder is consumed during engine operation, unrecoverable or unaccounted for (Meinhardt, 2002). The greatest potential for environmental release of the notified polymer is through disposal of oil product wastes. A survey by the Australian Institute of Petroleum (AIP 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases is disposed of responsibly (e.g. oil recycling or incineration). Assuming this is the case, negligible release of the notified polymer should result from these professional activities. The remaining 14% of oil (up to 0.42 tonnes of the estimated maximum 3 tonnes of notified polymer imported per annum) is removed by "do it yourself" (DIY) enthusiasts. In these cases, some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. Meinhardt (2002) estimated that DIY activities account for 7-10% of the unaccounted used oil.

According to a survey tracing the fate of used lubricating oil in Australia (Snow, 1997), only approximately 20% of used oil removed by DIY enthusiasts is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways. In a worst case scenario involving the 14% of used oil removed by DIY enthusiasts, the notified polymer could be collected for recycling (84 kg/y), buried or disposed of in landfill (105 kg/y), disposed of in stormwater drains (21 kg/y) and used in treating fence posts, to kill weeds or disposed of in other ways (210 kg/y). A proportion of the latter may potentially be disposed of to sewer. Therefore, about 0.7% (up to 21 kg/y) of the total import volume of the notified polymer could potentially enter the aquatic environment via disposal into the stormwater system. In addition to this, considering the unknown fate of some of the oil used by DIY operators, up to 7% (i.e. 50% of 14%; 210 kg/y) may also be sent to the sewer for disposal. Since the use of the lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of the notified material in neat concentrations is very unlikely except as a result of transport accidents. However, given that gearbox oils are changed by DIY enthusiasts relatively rarely, little is expected to be disposed of this way.

Spent packaging material and container residues are disposed of to landfill or incinerated. Emptied drums are likely to be cleaned with mineral oil and reconditioned, with oily waste potentially containing 2% of the formulation reused in subsequent batches or concentrated and incinerated. Emptied drums may also be collected for metal recycling. Assuming ~2% of the imported formulation remains in emptied drums, an estimated maximum quantity of 60 kg/y will be generated as waste by this route based on a total annual import volume of 3 t/y of the notified polymer.

6.3.2. Environmental Fate

The ultimate fate of the notified polymer depends upon its disposal method. If burnt, it will decompose to form simple compounds containing carbon, nitrogen and sulfur.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Viscous yellowish liquid.
Melting Point/Glass Transition Temp	Not determined.
Density	938 kg/m^3 at 15°C
Water Solubility	<1.5 mg/L at pH 2 at 20°C after 24 h; <1.5 mg/L at pH 7 at 20°C after 24 h; and 2.7 mg/L at 20°C at pH 9 after 24 h. Determined according to Korean Polymer Test

	Guidelines (similar to OECD 120). The test item was partitioned on the inner glass wall of the extraction flask and the content of dissolved organic carbon was measured. Water solubility is increased due to cationic nature of the polymer
Dissociation Constant	The notified polymer will be cationic at low pH values.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

No toxicological data for the notified polymer are available. However, the notifier has submitted a summary of the available toxicological data for several analogous polymers as read across data. Based on similar physical and chemical properties and monomeric composition the analogous polymers are expected to have similar toxicity profiles.

Endpoint	*Result*	*Classified as hazardous?*	*Effects Observed?*
Rat, acute oral LD50 >5000 mg/kg bw (Analogue 1)	low toxicity	no	Not provided.
Rat, acute oral LD50 >5000 mg/kg bw (Analogue 2)	low toxicity	no	Not provided.
Rat, acute oral LD50 > 5000 mg/kg bw (Analogue 4)	low toxicity	no	Not provided.
Rat, acute dermal LD50 >5000 mg/kg bw (Analogue 1)	low toxicity	no	Not provided.
Rat, acute dermal LD50 >5000 mg/kg bw (Analogue 2)	low toxicity	no	Not provided.
Rat, acute dermal LD50 >5000 mg/kg bw (Analogue 4)	low toxicity	no	Not provided.
Rabbit, skin irritation (Analogue 1)	non-irritating	no	Not provided.
Rabbit, skin irritation (Analogue 2)	slightly irritating	no	Not provided.
Rabbit, skin irritation (Analogue 3)	non-irritating	no	Not provided.
Rabbit, skin irritation (Analogue 4)	slightly irritating	no	Not provided.
Rabbit, eye irritation (Analogue 1)	slightly irritating	no	Not provided.
Rabbit, eye irritation (Analogue 2)	slightly irritating	no	Not provided
Rabbit, eye irritation (Analogue 3)	slightly irritating	no	Not provided
Rabbit, eye irritation (Analogue 4)	slightly irritating	no	Not provided
Rat, repeat dose Dermal toxicity – 14 days.(Analogue 1)	NOEL > 1000 mg/kg bw/day	no	yes

All results were indicative of low hazard.

8.1.1. Discussion of observed effects

In a 14 day repeat dose study analogue 1 was applied (10 applications) to the skin of rabbits at 0, 0.25, 0.50, 1.00 g/kg bw/day. Analogue 1 did not produce any systemic effect but did produce moderate to severe irritation at all doses.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted for the notified polymer. However, surrogate data was provided for the analogue product PA-4777, as shown below.

Endpoint	*Result and Conclusion*
Fish Toxicity (2 species)	EC50 >1000 mg/L *(Surrogate data)*
Daphnia Toxicity	EC50 4.1 mg/L *(Surrogate data)*

9.1.1. Discussion of observed effects

No comments as no test reports were presented.

9.2. Environmental Hazard Assessment

Based on the potentially cationic nature of the surrogate polymer, it is expected to be approximately 6 times more toxic to algae than to daphnids to which it is toxic. Cationic polymers with FGEW >5000 are not expected to be toxic to aquatic organisms. Since the full structure of the surrogate is not clear, any extrapolation to the notified polymer should be done cautiously. This has a FGEW >5000 and is not expected to be toxic to aquatic organisms.

10. RISK ASSESSMENT

10.1. Environment

The main environmental exposure is expected to result from inappropriate disposal of waste lubricant product by DIY enthusiasts, which will be however, widespread across Australia. Most of the improperly released notified polymer due to DIY activities is likely to become associated with soils or sediments, as will the notified polymer released to landfill including as container residues. Incineration of waste polymer will generate water vapour and oxides of carbon.

It is difficult to estimate the Predicted Environmental Concentration (PEC) of the notified polymer released into the aquatic environment via stormwater drains. However, a worst case PEC might be estimated if it is assumed that all of the 1% of the imported notified substance (i.e. 30 kg) expected to be released into the stormwater drains in a single metropolitan area with a geographical footprint of 500 square kilometres, an average annual rainfall of 50 cm. With a maximum annual release into this localised stormwater system of 30 kg and the annual volume of water drained from this region estimated to be approximately 250 X 10^6 m^3, the resultant PEC is approximately 0.12 μg/L. It should be stressed that this result is very much a worst case scenario, and that in reality releases of the polymer would be very much more diffuse than indicated here, and also at significantly reduced levels. Further, driveline oils are changed at worst only every 50000 km and mostly by specialists.

It is not possible to determine a predicted no effect concentration (PNEC) for aquatic ecosystems in order to assess the risk to aquatic organisms as no ecotoxicity data were provided. However, the use pattern of the notified polymer will result in limited and widespread exposure to the aquatic environment throughout Australia. As its FGEW is >5000, it is not expected to be toxic to aquatic organisms. Further, the low water solubility of the polymer and its potential to become associated with the sediments can expect to reduce the possibility of sufficient amounts to remain in solution to cause acute toxicity in the aquatic environment. While it can be assumed that the notified polymer will not degrade readily, it is likely to undergo slow biodegradation under environmental conditions.

The amount released to stormwater drains (less than 1% of the import volume) and enters the aquatic compartment could be expected to become associated with suspended organic material, settle out into the sediments and slowly degrade due to the biotic and abiotic processes. There is potential for the notified polymer to bioaccumulate due to its expected high log P_{ow} and the low water solubility but will be limited due to the high molecular weight, and the low and diffuse release to the aquatic environment Australia wide.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

10.3. Public Health

The driveline oil products containing the notified polymer will be available to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer, when changing the gearbox oil. However, the risk to public health will be negligible because the notified polymer is present at low concentrations and the result data provided is indicative of low hazard.

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

11.1. Environmental Risk Assessment

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

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

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

11.2.2. Public health

There is Negligible Concern to public health when used in the proposed manner.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of the notified polymer as introduced
  - Avoid drips and spills;
  - Use gloves, safety glasses and overalls
  - 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.

Environment

Disposal

- The notified polymer should be disposed of in accordance with all Local, State and Federal regulations at an approved waste disposal facility. This will include burning wastes and products containing the polymer in an enclosed, controlled burner for fuel value or disposed of by supervised incineration.
- Contaminated packaging should be emptied optimally and may be reused after appropriate professional cleaning. Packaging that cannot be cleaned should be disposed of professionally.

Emergency procedures

- Spills on non-solid ground (e.g. soil etc) should be removed mechanically. Spills on solid surfaces (e.g. concrete) should be absorbed with dry sand, possibly by heating. Dispose of contaminated material in accordance with regulations.
- The spilled material should be prevented from contaminating soil/subsoil and entering drains, surface water, ground water or wastewater.

13.1. 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 subsection 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 subsection 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.

14. BIBLIOGRAPHY

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Meinhardt (2002) Used oil in Australia. Prepared by Meinhardt Infrastructure & Environment Group for the Australian Government Department of the Environment and Heritage, Canberra.

Nabholz JV, Miller P and Zeeman M (1993) Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five. In: Landis WG, Hughes JS & Lewis MA ed Environmental Toxicology and Risk Assessment, ASTM STP 1179, American Society for Testing and Materials, Philadelphia, PA.

Snow R (1997) Used Oil Management. Paper presented at the Used Oil Management Conference, Brisbane, August 1997, Queensland Dept. Environment.