4 January 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Y-14570

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 and Heritage.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is 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

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. COMPOSITION	
4. INTRODUCTION AND USE INFORMATION	
5. PROCESS AND RELEASE INFORMATION	4
5.1. Operation Description	
6. EXPOSURE INFORMATION	
6.1. Summary of Occupational Exposure	
6.2. Summary of Public Exposure	
6.3. Summary of Environmental Exposure	
6.3.1. Environmental Release	4
6.3.2. Environmental Fate	
7. PHYSICAL AND CHEMICAL PROPERTIES	
8. HUMAN HEALTH IMPLICATIONS	
8.1. Toxicology	
8.1.1. Discussion of observed effects	
8.2. Human Health Hazard Assessment	
9. ENVIRONMENTAL HAZARDS	
9.1. Ecotoxicology	5
9.2. Environmental Hazard Assessment	
10. RISK ASSESSMENT	
10.1. Environment	
10.2. Occupational Health and Safety	
10.3. Public Health	
11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT	
HUMANS	
11.2. 114.1141 1144141 1100 1100 40011411	
11.2.1. Occupational health and safety	
12. MATERIAL SAFETY DATA SHEET	
12. MATERIAL SAFETT DATA SHEET	
12.1. Material Safety Data Sifet	
13.1. Secondary Notification	
13.1. Secondary Nouncation	/

FULL PUBLIC REPORT

Y-14570

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

GE Toshiba Silicones Australia Pty Ltd (ABN 47 105 651 063) of 175 Hammond Road 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 Identity, Polymer Constituents, Residual Monomers/Impurities, Import Volume, Use Details, Identity of Manufacturer/Recipients, and Process Description.

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

US EPA TSCA (1994)

China polymer exemption (2004)

Korea (2004)

Japan ENCS

Canada (submitted 2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Y-14930 (40-60% notified polymer) for use in pulp and paper applications

Y-14854 (40-60% notified polymer) for use in lube oils

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	Not applicable
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. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years Import

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

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

USE

As antifoam agent used in the pulp and paper industry and in marine lube oils.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will not be manufactured in Australia. It will be imported as the polymer itself or as a 40-60% component of antifoam emulsion products for use at low add-on levels in pulp mills or in marine lube oils blending.

In controlling foam, it is anticipated that these emulsion products will be dosed at a recommended dosage as required into a pulp mill or into an oil mixing tank. The finished lube oil (which is expected to contain <0.3% notified polymer) will be packed into liquid industrial containers of 1-200 L for use in heavy-duty marine diesels and not available to the general public.

In its application for pulp making, the notifier indicates that the antifoam will be washed off three times and thus no antifoam silicone is expected to be left on the pulp or adhere to the paper fibre.

6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

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

Public exposure through importation, transportation and storage is negligible. As a component of antifoam products for industrial use the notified polymer is not available to the general public.

6.3. Summary of Environmental Exposure

6.3.1. Environmental Release

The notified polymer is to be imported only and will not be manufactured in Australia. Environmental release may arise from accidental spills during transport and handling, however, these are expected to be minimal. Any spilt notified polymer should be physically contained, collected and subsequently disposed of to secure landfill or by thermal decomposition in an incinerator.

The notified polymer will be used in two industries. The major use will be as an antifoaming agent in the pulp and paper industry. The notified polymer will be added to the process water, however, it is not expected to adhere to paper fibre and will end up in the "black liquor". This will subsequently be

concentrated and disposed of by burning.

The minor use for the notified polymer is as an antifoaming agent for marine lube oil used in heavy duty commercial diesel engines. The oil is expected to gradually enter the engine combustion zone and be burnt.

Up to 1% notified polymer is expected to remain in containers, and is expected to be ultimately disposed of by thermal degradation in an incinerator or to secure landfill.

6.3.2. Environmental Fate

The environmental fate of used notified polymer is expected to be combustion, and subsequent thermal degradation to oxides of silicon and carbon. Notified polymer that is disposed of to an incinerator will also be thermally degraded to oxides of silicon and carbon. Notified polymer that is disposed of to secure landfill is expected to associate with sediments, and eventually degrade by biotic and abiotic process to simple carbon and silicon containing compounds.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Opaque, white semi solid

Melting Point >175°C

Density 990 kg/m³ (estimated)

Water Solubility Insoluble, although expected to be fully miscible.

Silicones are known for their insolubility.

Dissociation ConstantNot determined. There are no dissociable groups

present in the environmental pH range of 4-9.

Reactivity Stable under normal environmental conditions

Degradation ProductsNone under normal conditions of use

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological end-points were submitted:

Endpoint	Result	Classified?	Effects Observed?
Rat, acute oral LD50 >2000 mg/kg bw	low toxicity	no	yes
Genotoxicity – bacterial reverse mutation	non mutagenic	no	no

8.1.1. Discussion of observed effects

The acute oral toxicity of the notified polymer was evaluated via gavage in five male and five female albino rats at a single dose level of 2000 mg/kg. Clinical findings included hair loss and scabbing on the forelimbs. There were no deaths, remarkable body weight changes or gross necropsy findings.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The results of toxicity testing data submitted support this conclusion.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

9.2. Environmental Hazard Assessment

No ecotoxicity data were provided for the notified polymer. Nonionic polymers with a number average molecular weight in excess of 1000 are generally of low concern for ecotoxicity because they often have negligible water solubility.

10. RISK ASSESSMENT

10.1. Environment

While the notified polymer will be added to process water when used as an antifoaming agent in the pulp and paper industry, it is expected that the notified polymer will be subsequently concentrated and then burnt. Therefore, there should be no environmental release of the notified polymer from the pulp and paper industry. When used in marine lube oils, again, there should be no environmental release, as the notified polymer is expected to be burnt during diesel engine operation.

The majority of containers with residual notified polymer are expected to be sent to drum recyclers where the notified polymer will be removed and subsequently thermally decomposed in an incinerator. Any notified polymer that is disposed of to landfill is expected to associate with sediment, and eventually degrade through abiotic and biotic processes to simple silicon and carbon based compounds.

The polymer is not expected to cross biological membranes, due to its high molecular weight and low water solubility, and as such should not bioaccumulate. While no toxicity data are available, based on exposure and use pattern, the notified polymer is unlikely to pose an unacceptable risk to the environment.

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

As there will be no exposure of the public to the notified polymer or products containing the notified polymer the risk to the public from exposure to the notified polymer is considered negligible.

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

 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.

- 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.

Disposal

• The notified polymer should be disposed of to secure landfill or by thermal decomposition in an incinerator.

Emergency procedures

• Spills of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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) <u>Under subsection 64(1) of the Act</u>; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

- (2) <u>Under subsection 64(2) of the Act:</u>
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.