File No PLC/655

November 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Fixate G-100

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Lubrizol International, Inc (ABN 52 073 495 603)
28 River Street
Silverwater NSW 2128

Bronson and Jacobs Pty Ltd (ABN 81 000 063 249)
5 Parkview Drive, Australia Centre
Sydney Olympic Park NSW 2127

NOTIFICATION CATEGORY
Polymer of Low Concern

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point
Density
Flammability limits
Autoignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2001)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Z-74, Fixate G-100 polymer

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	>10000
% of Low MW Species < 1000	< 5
% of Low MW Species < 500	< 5

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. 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

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	The polymer in water is a translucent low viscosity, aqueous dispersion
Melting Point/Glass Transition Temp	Not determined. The notified polymer is supplied in an aqueous solution.
Density	1000 kg/m^3 (water)
Water Solubility	Dispersible in water, and expected to be soluble, which is consistent with its structure.
Dissociation Constant	Contains acid functionality expected to exhibit typical acidity (pKa ~4).
Particle Size	Supplied in an aqueous solution
Reactivity	Stable under normal environmental conditions. Has ester functionality which would not be expected to hydrolyse within the environmental pH range of 4-9.
Degradation Products	None under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	10-30	10-30

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The product containing the notified polymer (26% in water) is imported via sealed 208 L drums.

Reformulation/manufacture processes

The notified polymer is manufactured outside Australia. The product containing the notifier polymer is transported from the dock to customer warehouse directly.

A typical operation by customers would consist of blending the product containing the notified polymer with other personal care additives. The notified polymer will be pumped from the drums to a blend tank along with the other ingredients and mechanically mixed under local exhaust ventilation. The products will be pumped into a sealed tank which can be transferred to the packaging area of the plant. The final product containing the notified polymer will be pumped via pipes to the plastic retail containers ranging in size from 100 to 250 mL. These plastic containers will be packaged into cardboard boxes for shipment to the supermarket or retailer. The end use product will typically contain less than 3% of the notified polymer.

Use
In personal care applications, especially a hair fixative. The notified polymer is intended for use in non-aerosol styling products such as gels and creams.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

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 (local exhaust ventilation) and personal protective equipment worn by workers in addition to the low concentration of notified polymer in the imported product.

PUBLIC EXPOSURE
Personal care products containing the notified polymer at up to 3% by weight are for sale to the general public. Members of the public may make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, bioavailability is low because the notified polymer has a MW > 1000 therefore is unlikely to cross biological membrane.

6.2. Toxicological 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 notified polymer.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline*
1. Rat, acute dermal	LD50 > 2000 mg/kg bw	no	no	OECD TG 402
2. Rabbit, skin irritation	slightly irritating	no	yes	OECD TG 404
3. Rabbit, eye irritation	slightly to moderately irritating	no	yes	OECD TG 405
4. Skin sensitisation - human	no evidence of sensitisation.	no	yes	Shelanski & Shelanski Repeated Insult Patch Test

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY
The OHS risk presented by the notified polymer is expected to be low given its likely low hazard and predicted low exposure to workers involved in formulating personal care products due to a mostly closed system coupled with the use of PPE. 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.

PUBLIC HEALTH
The notified polymer is not available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health is negligible because the notified polymer meets the PLC criteria and the concentration of the polymer in personal care products is low (≤3%).

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Environmental release of the notified polymer is summarised in the following table.

Source of release	% Annual Volume	Released to
Residual notified polymer within 208 L import containers	<0.5%	landfill or trade waste sewer
Reformulation equipment cleaning and accidental spills	<1.5%	trade waste sewer
Residual notified polymer within 100-250 mL consumer containers	<2%	domestic landfill
Use of formulated products containing the notified polymer.	≥96%	domestic sewer

ENVIRONMENTAL FATE

Notified polymer that is disposed of to landfill is expected to be mobile due to its high water solubility. Over time, the notified polymer should degrade via biotic and abiotic processes to form simple organic compounds.

Notified polymer that is disposed of to sewer is expected to remain within the aquatic compartment, however, some may be removed within STPs.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the charged group is on alternating carbons of the polymer backbone. This could apply to the notified polymer. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups.

7.3. Environmental Risk Assessment

Since most of the polymer will be washed into the sewer, under a worst-case scenario without removal of the notified polymer in the STP, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is calculated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	30,000	kg/year
Proportion expected to be released to sewer	100.000%	
Annual quantity of chemical released to sewer	30,000.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	82.19	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	20.05	µg/L
PEC - Ocean:	2.01	µg/L

As no ecotoxicity data were provided, it is not possible to calculate a Predicted No-Effect Concentration (PNEC) nor determine the Risk Quotient (Q).

It is expected that some of the notified polymer will be adsorbed onto sewage plant sediments, and discharge from sewage treatment plants will be further diluted when released to inland and ocean waters. Also Binding to calcium ions would further reduce the risk. Further, the high molecular

weight and water solubility indicate a low potential to bioaccumulate.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

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

8.2. Level of Concern for Public Health

There is No Significant Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. 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.

10. 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.

Environment

Disposal

- The notified polymer should be disposed of by incineration or to secure landfill.

Emergency procedures

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

10.1. 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.