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

FULL PUBLIC REPORT

Z-63/Fixate Plus

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**Director
NICNAS**

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FULL PUBLIC REPORT**Z-63/Fixate Plus****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

Lubrizol International, Inc (ABN 52 073 495 603)
28 River St.
Silverwater NSW 2128

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 Formulae

Means of Identification

Molecular Weight

Polymer Constituents

Residual Monomers/Impurities

Reactive Functional Groups

Manufacture/Import Volume

Site of Manufacture

Purity

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

- particle size distribution
- flammability limits
- auto-ignition temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT

No

NOTIFICATION IN OTHER COUNTRIES

Notified in Canada.

Exempt from notification for use in pharmaceutical and personal care applications in US.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)

Fixate G-200

Fixate PLUS

EX-860

Fixate PLUS

MARKETING NAME(S)

Z-63

Fixate PLUS

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >10,000

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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	Milky white emulsion
Melting Point/Glass Transition Temp	>359.85 ± 0.5 °C Conducted in accordance with OECD Test Guideline 102
Density	1.06 x 10 ³ kg/m ³ at 20°C Conducted in accordance with OECD Test Guideline 109
Water Solubility	<9.20 x 10 ⁻⁵ g/L at 20°C Conducted based on OECD Test Guideline. 92 µg were added to 10L water, ultra sonicated at 20°C for 30 minutes and visually observed. Note that under these conditions, it is possible that the notified polymer may not have reached saturation equilibrium.
Dissociation Constant	Not determined. The notified polymer does not contain relevant functionality.
Reactivity	Stable at moderately elevated temperatures and pressures
Degradation Products	Stable and is not expected to undergo degradation under normal use and storage conditions

5. INTRODUCTION AND USE INFORMATION

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	0-1	0-1	0-1	1-3	1-3

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of introduction

Z-63 will not be manufactured in Australia. It will be imported as an emulsion containing 30% the notified polymer in water. It will be shipped either in 200 L drums or in 20 L pails. It is transported from the dock to the customer site via truck for reformulation or possibly repackaging. No repackaging occurs before reaching the customer site.

In the future, Z-63 may be imported as a component of finished personal care products such as a non-aerosol hair styling products which would contain approximately 0.5 to 2% the notified polymer. They would likely be transported in 200 to 500 mL plastic bottles, jars or tubes which would be shipped in cardboard boxes containing 24 to 96 of the jars or bottles. They would be transported from the dock to notifier's warehouse for distribution to retail shops by road. No repackaging would occur before the distribution.

Reformulation/manufacture processes

The Z-63 solution will be pumped directly from drums or pails to a blending tank where it will be blended with deionized water using gentle agitation. Conditioning and ancillary ingredients are then added and mixed, followed by addition of other additives such as fragrances, dyes, stabiliser etc. all these operations are expected to be carried out automatically or semi-automatically in a closed system. Sampling and analysis may be conducted during the formulation. The finished product will contain 0.5 to 2% the notified polymer and typically packaged into containers via an automatic packaging system.

Repackaging of Z-63 solution may occur at the formulation site, but the notifier indicated that this operation is unlikely.

End use

The notified polymer is used as a component of personal care products such as non-aerosol hair styling products, typically at 0.5 to 2%, by hair professionals and/or consumers. Z-63 functions as a polymer which combines hydrophilic, semi-hydrophilic and hydrophobic components.

Workers at retail shops and/or hair salons will unload the cardboard boxes from a truck and stack them in a storage room. When needed, workers will remove the finished product containing the notified polymer from the boxes and stack them on shelves for sale to the general public or for use in hair salons.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and ocular exposure may potentially occur during reformulation and repackaging processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is limited because of the fully or semi-automated processes, the engineering controls in place, and personal protective equipment worn by workers.

Intermittent, wide-dispersive use with direct handling is expected to occur among hairdressers, cosmeticians, and beauticians. However, workers exposure is limited due to low concentration in the finished product.

PUBLIC EXPOSURE

Since the notified polymer will be in products sold to the general public, widespread public exposure via hair and the skin is expected. Exposure to the notified polymer will vary depending on individual use patterns. Typically, 5 g of product containing up to 2% notified polymer is applied to the hair once or twice a day. It is estimated that a consumer using 5 g once daily would receive dermal exposure to 250 mg/day (5000mg x 2%) of the notified polymer. No information was provided on hair or dermal absorption. Assuming 10% absorption to a 60kg adult, systemic exposure would be 0.42 mg/kg/day (250 mg/day x 10% / 60kg). In addition, the high molecular weight would reduce the absorption of the notified polymer through the skin.

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 the following toxicological endpoints observed in testing conducted on a 30% emulsion of an analogue polymer which has similar structure with the notified polymer. This analogue has been accepted in the Canadian notification.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 >2000 mg/kg bw	No	No	OECD TG 423
2. Rabbit, skin irritation	Mild irritating	No	Yes	OECD TG 404
3. Rabbit, eye irritation	Mild irritating	No	Yes	OECD TG 405
4. Skin sensitisation (LLNA)	No evidence of sensitisation	No	Yes (enlarged nodes)	OECD TG 429 (LLNA)
5. Genotoxicity - bacterial reverse mutation	Non mutagenic	No	No	OECD TG 471

All results were indicative of low hazard. However, it should be noted that the USEPA has expressed concerns about lung damages (fibrosis of the lung or other pulmonary effects) that may be caused by inhalation of respirable particle of high molecular weight water solubility polymers <http://www.epa.gov/opptintr/newchems/pubs/hmwtpoly.html>.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer from the intended use is expected to be low, based on the minimal exposure to workers and the low intrinsic hazard of the polymer.

Although exposure to the notified polymer could occur during reformulation processes and direct handling by hairdressers, cosmeticians, and beauticians, the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

PUBLIC HEALTH

Although the public will be exposed to the notified polymer during use of the personal care product such as non-aerosol hair styling products containing the notified polymer, the risk to public health is considered to be low due to the predicted low hazard of the notified polymer and low concentrations (up to 2%) of the notified polymer in the finished product.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

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

<i>Source of Release</i>	<i>% Annual Import Volume</i>	<i>Released To</i>
Residual notified polymer within 200 & 20 L import containers	<1%	Landfill or trade waste sewer
Accidental spills	<1%	Incinerator
Reformulation equipment cleaning	<1%	Trade waste sewer
Residual notified polymer within 200-500 mL consumer containers	<2%	Landfill
Use of formulated products containing the notified polymer.	>95%	Domestic sewer

ENVIRONMENTAL FATE

The notified polymer that is disposed of by incineration is expected to be thermally decomposed to form simple oxides of carbon and hydrogen.

The notified polymer that is disposed to sewer is expected to associate with soil and sediment, with a proportion removed in waste water treatment plants.

The notified polymer that is disposed to landfill is expected to be immobile, due to its insolubility in water.

A Ready Biodegradability test was conducted according to OECD Test Guideline 301B. After 28 days, the notified polymer achieved 23% degradation, and while not ready biodegradable, demonstrates that it is inherently biodegradable. Therefore, it is expected that the notified polymer will eventually degrade via biotic and abiotic mechanisms to simple organic compounds.

7.2. Environmental Hazard Characterisation

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 acid is on alternating carbons of the polymer backbone. This could apply to the notified polymer. However, the toxicity to algae is likely to be reduced due to the presence of calcium ions, which will bind to the functional groups (Nabholz *et al.* 1993).

7.3. Environmental Risk Assessment

Since most of the polymer will be washed into the sewer, under a worst case scenario, with no removal of the notified polymer in the sewage treatment plant, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC)		
Annual quantity of polymer released to sewer	3,000	kg/year
Days per year where release occurs	365	days/year
Daily polymer release:	8.22	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	2.01	µg/L
PEC - Ocean:	0.20	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). However, anionic polymers are rarely toxic below 1 mg/L and therefore it is unlikely to pose an unacceptable risk to the aquatic environment.

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 for the notified polymer 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 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;
 - the notified polymer is proposed for use in spray products producing respirable particles.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.