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

FULL PUBLIC REPORT

**Z-69
Ultrabee 25**

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**Director
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FULL PUBLIC REPORT**Z-69
Ultrabee 25****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

Lubrizol International, Inc (ABN 52 073 495 603)
28 River St.
Silverwater NSW 2118

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

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT

No

NOTIFICATION IN OTHER COUNTRIES

Exempt from notification for use in personal care products in US.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Z-69, Ultrabee 25

INCI name: Bis-hydroxyethoxypropyl dimethicone beeswax esters

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn) >1000

REACTIVE FUNCTIONAL GROUPS

The notified polymer does not contain any reactive 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	Soft, off white solid
Melting Point/Glass Transition Temp	27.85 to 75.85 ± 0.5°C Conducted in accordance with OECD Test Guideline 102
Density	956 kg/m ³ at 20°C Conducted in accordance with OECD Test Guideline 109
Water Solubility	<6.00 x 10 ⁻⁴ g/L at 20°C Conducted based on OECD Test Guideline 105. 0.3, 0.4 and 0.7 mg were added to 500 mL 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.
Boiling Point	399.85 ± 0.5°C at 101.61-102.02 kPa Conducted in accordance with OECD Test Guideline 103
Auto-ignition Temperature	392 ± 5°C Conducted in accordance with Test Guideline A15 specified in the EU Commission Directive 92/69/EEC
Reactivity	Not an oxidizer. Does not contain any groups expected to be reactive
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>	1-3	1-3	1-3	3-10	3-10

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

Z-69 will not be manufactured in Australia. It will be initially imported as a neat material. 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 possible repackaging. No repackaging occurs before reaching the customer site.

Z-69 will be imported as a single component (30% in water) or as part of finished personal care products such as skin lotions, lip balms, cosmetic sunscreens or deodorants which would contain approximately 0.5 to 25% of the notified polymer. They would likely be transported in 10 to 500 mL plastic or glass jars or bottles 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

During formulation of the personal care products, Z-69 neat material will be warmed up to above 75°C before being pumped directly from drums or pails to a blending tank where it will be blended with other cosmetic additives. These operations are expected to be carried out semi-automatically in a closed system. Minimal heating is required during mixing. Sampling and analysis will be conducted during the formulation. The finished product containing 0.5 to 25% the notified polymer will be packaged into plastic or glass bottles or containers ranging in size from 10 to 500 mL via an automatic packaging system and then packaged into cardboard boxes for storage in warehouses before distribution to retail stores for sale.

Repackaging of Z-69 solution may occur at the formulation site, but the notifier indicated that this operation is unlikely.

End use

Z-69 functions as an emollient ester. It will be used in personal care products such as skin lotions, lip balms, cosmetic sunscreens or deodorants, typically at 0.5 to 25%, by beauticians and/or consumers.

Workers at retail shops and/or beauty 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 beauty 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 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 beauticians. According to EASE (1997) modelling of this work environment, dermal exposure in the range of 0.25-1.25 mg/cm²/day of products containing up to 25% of the notified polymer could result.

PUBLIC EXPOSURE

Since the notified polymer will be in products sold to the general public, widespread public exposure via the skin is expected. Exposure to the notified chemical will vary depending on product types and individual use patterns. The public dermal exposure to personal care products containing up to 25% the notified polymer are estimated for following product types:

Products	Use Level [#]	Dermal Exposure (mg/d)	Systemic Exposure* (mg/kg/day)
Skin lotions	8g, 2 time/d	4000 (16g x 25%)	6.67
Lip balms	0.01g, 4 time/d	10 (0.04g x 25%)	0.02
Cosmetic Sunscreens	10g, 75 time/y	513 [10g x (75 x/y / 365)x 25%]	0.85
Deodorants	0.5g, 1 time/d	125 (0.5g x 25%)	0.21

*Assuming 10% dermal absorption and a 60kg adult

[#] sourced from Bremmer et al. (2003)

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The table below summarises the toxicological endpoint observed in testing conducted on the notified polymer or polymer components or similar materials.

Endpoint	Result	Test substance	Classified	Effect s Observed	Test Guideline
1. Rat, acute oral	LD50 >5000 mg/kg bw	components or similar materials	No data	No data	From MSDS
2. Rabbit, acute dermal	LD50 >2000 mg/kg bw	components or similar materials	No data	No data	From MSDS
3. Rabbit, skin irritation	Not irritating	Notified chemical	No	No	OECD, US EPA and JMAFF
4. Rabbit, eye irritation	Slightly irritating	Notified chemical	No	*	OECD and US EPA
5. Skin sensitisation – LLNA test	Negative	Notified chemical	No	No EC ≥3 observed	OECD, US EPA and ICCVAM NIH
6. Skin sensitisation – Human Repeat Insult Patch test	No evidence of sensitisation	Notified chemical	No	No	None

* Grade 2 conjunctival irritation in 2/3 animals at 24h that disappeared by 48h
The notifier indicate that no data is available for the endpoint number 1-2.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Although exposure to the notified polymer could occur during reformulation processes and direct handling by beauticians, the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer. Accidental exposure is possible during transport of the notified chemical and reformulated products but risk is considered to be low due to the intrinsic low hazard of the notified polymer. The polymer is a slight eye irritant, however during formulation operations the risk is acceptable given that engineering controls are in place. The finished product with <25% of notified polymer is not expected to be irritating to the eyes.

PUBLIC HEALTH

Although the public will be exposed to the notified polymer during use of the finished product containing the notified polymer up to 25%, the risk to public health is considered to be low due to the predicted low hazard of the notified polymer.

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 & 20L import containers	<1%	Landfill or trade waste sewer
Accidental spills	<1%	Incinerator
Reformulation equipment cleaning	<1%	Trade waste sewer
Residual notified polymer within 10-500 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.

It is expected that the notified polymer will eventually degrade via biotic and abiotic mechanisms to simple organic and silicon based compounds.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. Non-ionic polymers with NAMW >1,000 are generally of low concern to the aquatic environment.

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 chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.4	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.438	million
Daily effluent production:	4,088	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	6.7	µg/L
PEC - Ocean:	0.67	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). The notified polymer is likely to be of non hazardous nature to the aquatic environment, with the PNEC being accordingly high. The resulting PEC/PNEC ratio will be very low. The risk of use of this notified polymer is, therefore, expected to be acceptable.

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 Low 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.
- 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.

11. BIBLIOGRAPHY

Bremmer HJ, Pru'homme de Lodder LCH, and Engelen JGM (2003) Cosmetics Fact Sheet to assess the risks for consumer. Draft RIVM report 6128100.../2003.

UK HSE (United Kingdom Health and Safety Executive) (2000) Estimation and Assessment of Substance Exposure (EASE) model (version 2.0 for windows). United Kingdom Health and Safety Executive.