File No SAPLC/96

August 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Rewoderm LI 520 (PEG-200 Hydrogenated Glyceryl Palmate)

This Self Assessment has been compiled by the applicant and adopted by NICNAS 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), administered by the Department of Health and Ageing and the Department of Environment, Water, Heritage and the Arts has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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:

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Procter & Gamble Australia Pty Limited (ABN 91 008 396 245)
Level 4, 1 Innovation Road, Macquarie Park, New South Wales 2113

NOTIFICATION CATEGORY
Self Assessment: 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, Molecular Weight, Polymer Constituents, Residual Monomers, Import Volume, Use and Mode of Introduction

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None known. The notified polymer is listed on TSCA, NDSL, KECI, NZIoC, PICCS.

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
V2999 for Rewoderm LI 520
PEG-200 Hydrogenated Glyceryl Palmate (INCI)
Antil 200 (product contains the notified polymer at up to 2%)

MARKETING NAME(S)
Rewoderm LI 520 as a component in Antil 200 (up to 2% notified polymer)

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (NAMW) > 1000 Da

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
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:	Solidified mass
Melting Point	~58°C
Density	1,170 kg/m^3 at 25°C
Water Solubility	5 g/L at 20°C (No clouding opacity at this level. Method not disclosed but consistent with structure.)
Reactivity	Contains hydrolysable functionalities but expected to be stable under normal 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	< 2	< 2	< 2	< 2	< 2

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported as a component of ready-to-use skin cleansing formulations.

Reformulation/manufacture processes

Reformulation/manufacture will not occur in Australia. The product is manufactured in France.

Use

Component of face scrubs and washes for general consumer use at up to 2%. The polymer will function as a surfactant.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

When imported as part of finished personal care products, occupational exposure is not expected except in an unlikely case of accident during transport and storage.

PUBLIC EXPOSURE

Based on the results from toxicity testing on a similar polymer it is expected that the notified polymer may have some skin and eye irritating potential at high concentrations. However this is not expected at concentrations close to that used in the imported products (up to 2%). Although the notified polymer will be sold to the general public and widespread public exposure is expected, the level of exposure is expected to be low as the products containing the notified polymer are intended for wash-off

immediately following application.

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 a close analogue polymer where all results were indicative of low hazard.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline (Choose one)*
1. Rat, acute oral	LD50 >5000 mg/kg bw	no	no	In house method consistent with OECD TG 401. No GLP statement.
2. Rabbit, skin irritation		no		In house method
100% notified polymer	Slightly irritating		yes*	consistent with
5% notified polymer in water	Non-irritating		no	OECD TG 404. No GLP statement.
3. Rabbit, eye irritation		no		In house method
100% notified polymer	Slightly irritating		yes**	consistent with
5% notified polymer in water	Non-irritating		no	OECD TG 405. No GLP statement
4. Skin sensitisation - adjuvant test (70% at challenge)	No evidence of sensitisation.	no	no	OECD TG 406 (Maximisation test)

* Irritation score 0.3 (mean from three animals after 24h). Irritation score was 0 at 72h.
** Doubtful or barely perceptible injection of the vessels in 1/6 animals and vessels definitely injected above normal in 3/6 animals at 24h. At 48h only doubtful or barely perceptible injection of the vessels in 3/6 animals was observed. By 72h no reaction was observed in any animal.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

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

PUBLIC HEALTH

Considering the intrinsic low toxicity of the notified polymer and the likely low exposure, the risk for the general public from the use of the products containing the notified polymer is not considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The formulated product will be applied to skin. Therefore, the majority of the notified polymer is expected to be washed off and enter the sewer, where it should mainly remain in the water column with the remainder disposed of in landfill as residues in product containers. Sludge containing the polymer will be disposed of in landfill

ENVIRONMENTAL FATE

The notified polymer is water soluble, expected to be hydrolytically stable and not expected to be readily biodegradable. On the basis of water solubility, the notified polymer is likely to be mobile in soils, but mobility may be retarded by the expected surface activity. The notified polymer should not hydrolyse but is expected to slowly degrade into oxides of carbon and water. Incineration of the notified polymer will result in the generation of water vapour and carbon dioxide. The notified polymer's high molecular weight will preclude absorption across biological membranes and thus it is unlikely to bioaccumulate.

7.2. Environmental Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified polymer (70% in water).

Endpoint	*Result*	*Effects Observed?*	*Test Guideline (Choose one)*
Fish Toxicity	EC_{50} >6990 mg/L	no	OECD TG 203
Daphnia Toxicity	EC_{50} >6990 mg/L	no	OECD TG 202
Algal Toxicity	E_bC_{50} >6990 mg/L E_rC_{50} >6990 mg/L	no	OECD TG 201
Aerobic Biodegradation Test (Biodegradation after 42 days)	48-79%	yes	OECD TG 303 A
Anaerobic Biodegradation Test (Biodegradation after 60 days)	40-50%	yes	GLP, EN 45001 and ISO 11734

All results are indicative of low hazard. The biodegradation tests indicate only partial degradation under aerobic and anaerobic conditions.

7.3. Environmental Risk Assessment

The formulated product will be applied to skin. Therefore, the majority of the notified polymer is expected to be washed off and enter the sewer, where it should mainly remain in the water column with the remainder disposed of in landfill as residues in product containers. Some retention on sludge may be expected as the notified polymer is likely to be surface active. Sludge containing the polymer will be disposed of in landfill.

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The products containing the notified polymer are likely to be used throughout Australia. Based on the proposed use pattern, the release of the notified polymer to the aquatic environment is expected to be low and dispersed. Adsorption to sludge, soil, and sediment as well as degradation and dilution in sewage treatment plants and receiving waters should ensure that environmental concentrations remain at acceptable levels.

Given the above, environmental exposure and the overall environmental risk are expected to be low.

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

8.3. Level of Concern for the Environment

The chemical 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.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
  - Protect from freezing

Emergency procedures

- Spills/release of the notified polymer should be soaked into an absorbent material and collected for safe disposal.

11. REGULATORY OBLIGATIONS

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 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 Section 64(2) of the Act; if

- the function or use of the chemical has changed from component of face scrubs and washes for general consumer use at up to 2%, or is likely to change significantly;
- the amount of chemical being introduced has increased from 2 tonne per year, or is likely to increase, significantly;
- if the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.