

File No PLC/736

April 2008

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

FULL PUBLIC REPORT

**Rewoderm LI 520
(PEG-200 hydrogenated glyceryl palmate)**

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, Water, Heritage and the Arts.

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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FULL PUBLIC REPORT**REWODERM LI 520
(PEG-200 hydrogenated glyceryl palmate)****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

Galderma Australia Pty Ltd (ABN 12 003 976 930)
13B Narabang Way
Belrose NSW 2085

Salkat Australia Pty Ltd (ABN 30 318 540 786)
262 Highett Road
Highett VIC 3190

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, Molecular Weight, Polymer Constituents, Residual Monomers

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

None

NOTIFICATION IN OTHER COUNTRIES

None known. The notified polymer is listed on TSCA, NDSL, KECI, NZIoC, PICCS.

2. IDENTITY OF CHEMICAL

MARKETING NAME

REWODERM LI 520, also supplied as component in product REWODERM LI S 80

INCI NAME

PEG-200 hydrogenated glyceryl palmate

OTHER NAME

V 2999

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >1000 Da

3. PLC CRITERIA JUSTIFICATION

Criterion	Criterion met
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	N/A
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 polymer (100%) Over Next 5 Years

Year	1	2	3	4	5
Tonnes	33	33	3	33	33

Use

Component of shampoos and body washes at up to 8%. The polymer will function as an emulsifier and viscosity improver.

Mode of Introduction and Disposal

The notified polymer will be imported as a component of a ready-for-use skin cleansing formulation, Cetaphil Oily Skin Cleanser in sample and trade size packs from 4 mL to 500 mL. The polymer will also be imported for formulation of other shampoo and body wash products in Australia.

6. HUMAN HEALTH IMPLICATIONS

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 chemical where all results were indicative of low hazard.

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

Occupational Health and Safety Risk Assessment

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. Where the polymer is imported, worker exposure may occur during formulation and packaging of personal care products, however this is expected to be minimised by standard controls at the reformulation sites. Overall, 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 Risk Assessment

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 (8%). 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. The product label directions for use specify that small amount should be applied to wet skin and washed off.

Therefore, 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 considered acceptable.

7. ENVIRONMENTAL IMPLICATIONS

- 7.1 ENVIRONMENTAL RELEASE Losses during formulations are expected to be small. There may be some release to the sewer but amount will be low compared with release during use.

The formulated product will be applied to hair or 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.

- 7.2 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. 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.

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)

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed</i>	<i>Test Guideline</i>
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 _b C ₅₀ > 6990 mg/L E _r C 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. Full test reports were provided for all studies. The biodegradation tests indicate only partial degradation under aerobic and anaerobic conditions.

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. Sludge containing the polymer will be disposed of in landfill.

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. 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.

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 Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis, Predicted No-Effect Concentration (PNEC) and Risk Assessment (Q) are estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment

Total Annual Import/Manufactured Volume	33,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	33,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	90.41	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	21.36	µg/L
PEC - Ocean:	2.14	µg/L

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment

EC50	6,990.00	mg/L
Assessment Factor	100.00	
Mitigation Factor	1.00	
PNEC:	69,900.00	µg/L

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	21.36	69900	0.0003
Q - Ocean:	2.14	69900	0.00003

As the PEC/PNEC ratio is considerably less than 1, there should be a low risk to aquatic organisms

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 receiving waters should reduce environmental concentrations to acceptable levels.

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

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

Under the conditions of the occupational settings described and when used in the proposed manner, the notified polymer is not expected to pose an unreasonable risk to workers and the public.

Environmental risk assessment

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

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 *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], 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 and/or accidental release of the notified polymer should be soaked into an absorbent material.

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 polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer 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(2) of the Act; if
 - the function or use of the chemical has changed from ingredient in wash off personal care products, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 33 tonnes, 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.

Material Safety Data Sheet

The MSDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.