File No PLC/1020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Abil Wax 9801
(Cetyl dimethicone)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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

October 2011

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1020	Salkat Australia Pty Ltd The Trustee for Wise Thomas Unit Trust	Abil Wax 9801 (Cetyl dimethicone)	No	≤5 tonnes per annum	Component of personal care and cosmetic products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- 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.

Environmental Recommendations

- No specific control measures are required to minimise release of the notified polymer to the environment.

Disposal

- The notified polymer should be disposed to landfill.

Storage

- The following precautions should be taken by workers regarding storage of the notified polymer:

- Store in a segregated and approved area.
- Store in original container protected from direct sunlight in a dry, cool and well ventilated area, away from incompatible materials (oxidising substances, strong acids, strong bases).

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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 polymer 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(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 notified polymer has changed from a component of personal care and cosmetic products , or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- the notified polymer has begun to be manufactured in Australia;
- the method of manufacture of the notified polymer in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the notified polymer on occupational health and safety, public health, or the environment;
- additional information has become available to the person as to an adverse effect of the notified polymer 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 was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Salkat Australia Pty Ltd (ABN 30318 540 786)
262 Highett Road,
Highett VIC 3190

The Trustee for Wise Thomas Unit Trust
Crn Wellington and Jacksons Road
Mulgrave VIC 3170

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, molecular weight, polymer constituents, residual monomers/impurities and manufacture/import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
Abil Wax 9801 (Cetyl dimethicone)

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 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	Clear to yellow liquid
Melting Point/Glass Transition Temp	<15°C
Density	865-885 kg/m^3 at 25 °C
Water Solubility	8 mg/L at 25 °C, pH 4.5
Particle Size	NA
Reactivity	Stable under normal environmental conditions
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	<5	<5	<5

Use
The notified polymer will be used as an emollient in personal care and cosmetic products.

The notified polymer will be imported either as neat polymer or as a component of finished products at 1% concentration. The neat notified polymer will be reformulated into personal care or cosmetic products at 2-10% concentration.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50> 5000 mg/kg bw	no	OECD TG 425, OPPTS 870.1100
2. Rabbit, skin irritation	Slightly irritating	yes	FHSA* Protocol no. 002/P201

*Federal Hazardous Substances Control Act

All results were indicative of low hazard.

Dermal Exposure
The notified polymer was tested for cutaneous penetration and absorption through pig skin in vitro. It was found with all skin discs that no notified polymer could pass through the skin barrier up to the detection limit (<0.1µg/ml) at collection times of 0, 16, 24 ,40, 40, 64 and 72 hours (1st and 2nd experiment). Based on the detection limit, it was concluded that the cutaneous permeation of the notified polymer was < 0.0071% (1st experiment) and <0.0143% (2nd experiment).

Acute Oral Toxicity
An acute oral toxicity test (Up and Down Procedure) was conducted with rats. An initial limit dose of 5000 mg/kg bw was administered to one healthy female rat by oral gavage. Due to the absence of mortality in this animal, two additional females received the same dose level. Since these animals survived, no additional animals were tested. All animals survived, gained body weight, and appeared active and healthy during the study. There were no signs of gross toxicity, adverse pharmacologic effects, or abnormal behaviour. No gross abnormalities were noted for any of the animals, when necropsied at the conclusion of the 14-day observation period.

Skin Irritation
The skin irritation potential of the neat notified polymer was tested in six New Zealand White rabbits. The test material was applied under occluded dressing to the shaved skin (abraded and intact sites) for 24 hours. Observations were made at 24 and 72 hours. All animals appeared active and healthy. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behaviour. Very slight erythema (barely perceptible) was observed in abraded and intact skin at 24 hours, which was not observed at 72 hours. No oedema formation was observed in both types of skin at 24 or 72 hours observations.

The notifed polymer has not been tested for its mutagenic or skin sensitization potentials. However based on the in-vitro permeation study on pig skin and on the interrelation between penetration,

molecular weight and the toxicological effect, the notifier has concluded that the notified polymer is unlikely to be a mutagenic or skin sensitizer.

Occupational Health and Safety Risk Assessment
The notified polymer meets the PLC criteria and is therefore assumed to be of low health hazard. This is further supported by the limited toxicological data provided and a very low cutaneous penetration of the notified polymer. However, based on the toxicological studies provided by the notifier, the notified polymer may present as a slight skin irritant.

Given the concentration in end use products is ≤ 10%, workers most at risk of slight skin irritation effects will be workers handling the neat notified polymer. These workers are expected to wear PPE such as safety glasses, gloves and protective clothing, which should minimise exposure and hence risk.

Overall based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers. However, given the notified polymer may have the potential for slight skin irritation, workers should take steps to avoid skin contact when handling the neat notified polymer.

Public Health and Safety Risk Assessment
There will be widespread and repeated exposure of the general public to the notified polymer through the use of personal care and cosmetic products. The principal route of exposure will be dermal and ocular.

The notified polymer may be present as a slight skin irritant. However, given the low concentration (≤ 10%) of the notified polymer in consumer products, the risk of irritation is expected to be low.

Overall, based on the assumed low hazard and assess use pattern, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment.

The majority of the notified polymer will be released to sewer as a result of its use in personal care and cosmetic products that will be washed off the hair and skin. Release is assumed to occur daily, and to be diffuse in nature. A predicted environmental concentration in rivers (PEC_{river}) can be calculated on the assumptions that 100% of the total annual import volume is released to sewer nationwide but that 90% of the notified polymer is removed by sewage treatment plant (STP) processes. The PEC_{river} is 0.30 μg/L if the daily chemical release (5000 kg/365 = 13.7 kg) is diluted by the daily effluent production (200 L/person/day × 22.613 million people = 4,523 ML). The remainder of the notified polymer partitions to biosolids with an estimated concentration of 27.261 mg/kg (dry wt), and is expected to be disposed of to landfill or applied to agricultural soils for soil remediation.

Release of the notified polymer to the aquatic environment is not expected during reformulation as residues in equipment washings and import containers are expected to be collected and disposed of by licensed waste disposal contractors. Some of the notified polymer may remain in residues in end-use containers and these are expected to be disposed of to landfill.

When applied to agricultural soils in biosolids or disposed of to landfill, the notified polymer is expected to associate with soil and organic matter and be largely immobile. The notified polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate. The notified polymer is expected to eventually degrade to form water and oxides of carbon and silicon.

Therefore, based on its assumed low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.