File No SAPLC/127

December 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with ethylenediamine and stearyl alc.

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 Sustainability, Environment, Water, Population and Communities have 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 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

TABLE OF CONTENTS

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
SAPLC/127	Bronson and Jacobs Pty Ltd	Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with ethylenediamine and stearyl alc.	No	≤5 tonnes per annum	Component of personal care products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human health risk assessment
Based on the available data and the reported 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 reported use pattern, the notified polymer is not considered to pose a risk to the environment.

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

- The following control measures should be implemented by personal care formulators to minimise environmental exposure during reformulation of the notified polymer:
  - Bunding

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills/release of the notified polymer itself should be handled by physical containment, collection and subsequent safe disposal.

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 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 chemical, 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 products, or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the notified polymer has begun to be manufactured in Australia;
- 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 notifier has provided an MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Bronson & Jacobs Pty Ltd (ABN: 81 000 063 249)
70 Marple Ave
Villawood, NSW 2163

NOTIFICATION CATEGORY
Self Assessment: Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Polymer Constituents, Residual Monomers/Impurities, Introduction Volume

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (1997), Canada (2000), Korea (2011), China (2010)

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Fatty acids, C18-unsatd., dimers, hydrogenated, polymers with ethylenediamine and stearyl alc.

OTHER NAME(S)

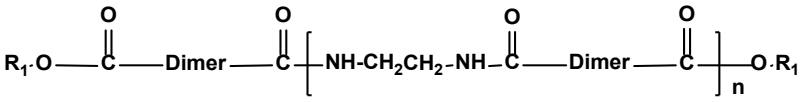
Ester-terminated Polyamide
Ethylenediamine/Stearyl Dimer Dilinoleate Copolymer (INCI name provided by notifier)

MARKETING NAME(S)
UNICLEAR™ 100VG

CAS NUMBER
951153-32-5

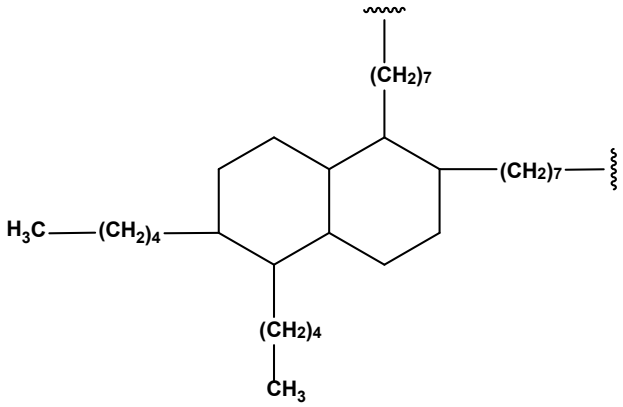
MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA
The notified polymer may be represented by the following structural formula:



Where $R_1 = CH_3(CH_2)_{16}CH_2$-

and Dimer =



MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW)	3210 Da
Weight Average Molecular Weight (WAMW)	6469 Da
Polydispersity Index (WAMW/NAMW)	2.0
% of Low MW Species < 1000	4.8
% of Low MW Species < 500	2.2

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	Light yellow solid in pastille form
Melting Point/Glass Transition Temp	90-97°C softening point
Density	990 kg/m^3
Water Solubility	<13 mg/L or <0.13% at pH 7. Test substance was stirred with double distilled water at a nominal concentration of 10.0 g/l. Samples were taken from each water mixture at 24, 48, and 72 hours of stirring. Undissolved test substance was removed by centrifugation and the aqueous phases were analyzed for the polymer by TOC analysis. Temperature of climate room was 19.8±0.6ºC.
Dissociation Constant	Not determined. Expected to be pKa ~ 4.9 based on the estimated value for residual carboxylic acid functional groups.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

Comments
In a parallel water solubility/extractivity study, mercuric chloride was also present to prevent any biodegradation. The same result was found - <0.13%. Hence it was concluded that the notified polymer has no appreciable solubility in water and also that it contains essentially no water extractable components.

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-5	1-5	1-5	1-5	1-5

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction
The notified polymer will be imported at 100% concentration in heat sealed, multi-ply polyfoil bags, 20 kg net wt.; 20 bags per pallet, 400 kg net wt. It will be imported via Sydney harbour and transported by truck (road transport) to the importer's warehouse for storage or directly to customers for reformulation.

Reformulation/manufacture processes
Reformulation will occur in Australia at various sites. Reformulation will involve manual weighing of the notified polymer, followed by automated mixing with other ingredients at approximately 85ºC until completely dispersed, cooling to room temperature, and filling of small containers for retail sale. The reformulated personal care topical lotion will contain 1-5% notified polymer and will be in liquid or gel form.

Use
The notified polymer will be used as a rheology modifier or film former at 1-5% in personal care topical lotions for consumer use.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE
Transport and storage workers may come into dermal contact with the notified polymer pastilles only through accidental breakage of bags.

During reformulation, workers may be exposed via the dermal route to the notified polymer pastilles during manual weighing and charging of the polymer to the mixing vessels. Dermal and inhalation exposure to vapours from heated mixture containing 1-5% notified polymer may occur during the mixing/dispersing step. However, exposure to significant amounts of the notified polymer will be limited due to the workplace practices and personal protective equipment typically used during these operations.

PUBLIC EXPOSURE

Since the notified polymer will be in topical personal products (lotions) sold to the general public (at up to 5% concentration), widespread public exposure is expected. Exposure to the notified polymer will vary depending on individual use patterns.

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 the notified polymer or analogue chemical.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD_{50} >5000 mg/kg bw	no	no	OECD TG 401
2. Rabbit, skin irritation	Non-irritating	no	no	OECD TG 404
3. Rabbit, eye irritation	Minimally irritating	no	yes	OECD P324
4. Skin sensitisation	Essentially non-irritating and did not elicit evidence of induced contact sensitization	no	no	HRIPT

All results were indicative of low hazard.

In the eye irritation study, the Maximum Mean Total Score was 2.0. No corneal opacity or iritis were noted during the study. One hour after test substance instillation, three out of three treated eyes exhibited conjunctivitis. The incidence and severity of irritation decreased with time. All animals were free of ocular irritation within 72 hours.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer is not considered to be unreasonable, based on minimal exposure to workers and the assumed low hazard of the notified polymer.

PUBLIC HEALTH

Although the public will be exposed to the notified polymer during use of the personal care topical lotions, the risk to public health is not considered to be unreasonable due to the assumed low hazard of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release to the environment during shipping, transport and warehousing of the notified polymer will only occur through accidental spillage from broken bags. Spills are expected to be collected and disposed to landfill.

During formulation, a small amount of notified polymer could be washed from machinery during cleaning. This is expected to be treated as site industrial waste and dealt with by licensed disposal contractors. Empty bags with any remaining residual material will be disposed of to licensed landfill.

The formulated personal care product will be applied to skin. Therefore, the majority of the notified polymer is expected to be washed off and enter the sewer, with the remainder disposed of in a landfill as residues in product containers.

Under a worst case scenario it is assumed that 100% of the notified polymer may be released to sewers and not removed during sewage treatment processes. However, this release will be dispersed throughout Australia and therefore the concentration of the notified polymer reaching the sewage treatment plants would be a maximum of 3.03 µg/L on a nation wide basis (5 tonnes/22.61 million × 200 L per person per day × 365 days). However, the notified polymer is expected to be removed by sewage treatment plant (STP) processes by up to 90% by sorption to sludge and sediments.

ENVIRONMENTAL FATE

The notified polymer was not readily biodegradable when tested according to modified Sturm test, based on EEC Directive 92/69, C.4-C, December 1992 and OECD Guideline 301 B July 17, 1992. A toxicity control showed that the test substance was not inhibitory to microbial activity and hence the lack of biodegradation is not due to toxicity. The finding that the notified polymer showed no evidence of any ready biodegradability is likely due to the evidence that essentially no components were extractable into water. This biodegradability study was a relatively short-term aerobic study carried out under "non-forcing" conditions and the component monomers would be expected to be inherently biodegradable; therefore, it is entirely possible that a longer exposure under more forcing aerobic or the anaerobic conditions to be found in landfills and sewage sludge digesters may lead to some degradation.

Due to its low water solubility, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen. If spilt to land, the notified polymer is expected to bind to soil and become immobilised in the soil layer. When released to sewer, it is not expected to dissolve but rather disperse or settle to sediment and to be landfilled. Bioaccumulation of the notified polymer is not likely as it is not expected to cross biological membranes based on its high molecular weight.

7.2. Environmental Hazard Characterisation

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

7.3. Environmental Risk Assessment

Release of the notified polymer to the aquatic environment is expected to be low and dispersed as the majority of the notified polymer disposed of to sewer through wash off of cosmetic products is likely to be removed during sewage treatment plant processes. In addition, polymers without significant ionic functionality are of low concern for the environment. Notified polymer in solid wastes and sludge disposed of to landfill is likely to remain immobile and slowly degrade. 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.