File No PLC/826

April 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in SIMULGEL SMS 88 (Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer)

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Polymer in SIMULGEL SMS 88
(Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Bronson and Jacobs Pty Ltd (ABN 81 000 063 249)
70 Marple Avenue
VILLAWOOD NSW 2163

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, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details.

NOTIFICATION IN OTHER COUNTRIES
Canada (2008).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in SIMULGEL SMS 88
Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer (INCI Name)
SIMULGEL SOS

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10,000 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*: Viscous, translucent/opaque white to yellow emulsion

Melting Point/Glass Transition Temp	> 200°C
Density	1,100 kg/m^3 at 25°C
Viscosity	60,000 – 100,000 mPa.s at 25°C (3% SIMULGEL SMS 88 in deionised water)
Water Solubility	Not determined. The notified polymer is crosslinked and hence is insoluble in water. However, it is dispersible in water and forms a gel.
Dissociation Constant	Not determined. The notified polymer contains salt of a strong acid and acidic groups would be expected to remain dissociated throughout the environmental pH range of 4 to 9.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use. The notified polymer contains functional groups of potential hydrolysis in the environmental pH range of 4-9.

* For SIMULGEL SMS 88 (contains < 45% notified polymer)

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
SIMULGEL SMS 88 will be used as a viscosity-increasing agent, thickener stabiliser and emulsion stabiliser for a range of cosmetic and personal care products at concentrations up to 5%.

Mode of Introduction and Disposal
The notified polymer will be imported into Sydney by sea as a component of the formulation SIMULGEL SMS 88 (< 45%). The formulation will also contain Isohexadecane (CAS No. 27235-48-9), Polysorbate 60 (CAS No. 9005-67-8) and Water.

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 5% SIMULGEL SMS 88.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Skin irritation - human volunteers	non-irritating	yes	EEC Directives 91/507 and III 3976/88
HET-CAM, eye irritation	non-irritating	no	Internal procedure
Skin sensitisation – human volunteers	no evidence of sensitisation.	yes	Marzulli-Maibach Method
Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471
Red blood cell aggregation test	negative	no	Internal procedure

All results were indicative of low hazard.

Skin irritation
A 48-hour occlusive patch test using 5% SIMULGEL SMS 88 in water was conducted on 20 healthy volunteer adults (18 F, 2 M) according to EEC Directives 91/507 and III 3976/88 of 11/07/1990. Readings were taken 30 minutes, 24 hours and 48 hours after application. A mean irritation index (MII) was calculated for each time point as 0, 0.18 and 0 respectively. At the 24-hour time point, barely visible erythema was observed in 5 volunteers and slight erythema was observed in 1 volunteer. However, no signs of erythema were observed in any of the volunteers at the 48-hour time point.

Skin sensitisation

A 6-week study on the skin irritation and sensitising potential of 5% SIMULGEL SMS 88 in water was conducted in 50 healthy human volunteers (42 F, 8 M) aged 18 – 65 years according to the Marzulli-Maibach Method (EEC Directives 91/507 and III 3976/88 of 11/07/1990). Eight readings for irritation and sensitising potential were taken approximately 48 hours apart during the 3-week induction phase, then after a 2-week rest phase 2 readings were taken during the 48-hour challenge phase (on days 38 and 40). One reaction considered indicative of erythema/oedema was observed in one volunteer on Day 40. Under the conditions of the test 5% SIMULGEL SMS 88 in deionised water did not indicate irritation or sensitisation potential.

Eye irritation – Hens Egg Test-Chorio-Allantoic Membrane (HET-CAM)
0.3 mL of a formulation containing 5% SIMULGEL SMS 88 in deionised water was applied to the chorio-allantoic membrane of an unspecified number (either 4 or 6) Leghorn hens' eggs according to an internal study procedure. No signs of hyperaemia, haemorrhage or coagulation were observed in any of the membranes tested. Therefore, 5% SIMULGEL SMS 88 was not considered an eye irritant under the conditions of the test.

Genotoxicity
5% SIMULGEL SMS 88 was found to be negative in a bacterial reverse mutation assay (Ames test), conducted both with and without metabolic activation at concentrations up to 5000 μg/plate according to OECD TG 471. No evidence of reduction of the background lawn or cytotoxicity was observed during the test.

Red blood cell aggregation
5% SIMULGEL SMS 88 tested in deionised water with 0.4% NaCl was found not to have denaturing or hemolysing properties when applied to red blood cells during a red blood cell aggregation (RBCA) test conducted according to an internal procedure.

Occupational Health and Safety Risk Assessment
Reformulation into cosmetic and personal care products
The notified polymer (< 45%) as imported in an emulsion will be weighed and added into a blending vessel where it will be pre-heated prior to formulation. Dermal and ocular exposure may result from spills, drips and splashes during weighing and transferring the emulsion containing the notified polymer into the mixing vessel.

Mixing is expected to take place in a fully automated, enclosed, mixing vessel and as such, exposure is not anticipated.

After mixing, packaging of cosmetic and personal care products containing the notified polymer (≤5%) is expected to take place using automated filling equipment. However, accidental dermal and ocular exposure may result from spills, drips and splashes.

Accidental dermal exposure to a small quantity of the finished product containing the notified polymer may also occur during quality testing.

Workers involved in reformulation and quality assurance will be expected to wear appropriate Personal Protective Equipment (PPE), including safety glasses and chemical resistant gloves to minimise the potential for exposure. In addition, reformulation sites are expected to be fitted with exhaust ventilation to minimise any vapours or aerosols generated during reformulation.

Professional use of finished cosmetic products
Beauticians and hairdressers will experience dermal and ocular exposure during application of various cosmetic and personal care products containing the notified polymer (≤ 5%). The level and route of exposure will vary depending on the product, method of application and work practices employed. Exposure is not expected to be significant given the low concentration of the notified polymer in finished products.

Overall, the OHS risk presented by the notified polymer is not expected to be unacceptable, based on the expected low exposure to workers and the low potential for toxicity following dermal and ocular exposure as indicated by the toxicological tests supplied by the notifier.

Public Health Risk Assessment
The notified polymer will be used in cosmetic and personal care products such as skin care products at ≤ 5%. Exposure to the notified polymer will vary depending on individual use patterns.

Although the public will be exposed to the notified polymer during use of cosmetic and personal care products, the risk to public health is not considered to be unacceptable given the low potential for toxicity vial dermal and ocular routes as indicated by toxicological tests provided by the notifier. In addition, the public may also accidentally ingest products containing the notified polymer (≤ 5%). There are no repeat dose oral toxicity data on the notified polymer, however, based on its expected low bioavailability, it is not anticipated to pose an unacceptable risk via the oral route.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation
The notified polymer can be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Effects Observed?*	
Fish Toxicity	LC50 > 100mg/L (WAF)	No	OECD TG 203
Daphnia Toxicity	EC50 > 100 mg/L (WAF)	No	OECD TG 202

All results were indicative of low hazard up to the solubility of the notified polymer in water. However, the notified polymer contains anionic groups, to which algae is the most sensitive species. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. Whether this applies to the notified polymer is unclear. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups.

Environmental Risk Assessment

Up to 97% of the notified polymer will go to sewage treatment and 37% will go to landfill with the empty containers. Assuming 90% of the notified polymer will be removed via sludge absorbing in the STP, which is common for polymers containing anionic charges, the predicted environmental concentration (PEC) of the notified polymer will be 0.12 µg/L. By using the endpoint of LC50 of > 100 mg/L for fish, and an assessment factor of 1000, the predicted no-effect concentration (PNEC) for the notified polymer in water is predicted to be above 100 µg/L. And therefore, the risk quotient Q (PEC/PNEC) is calculated to be < 0.01.

The notified polymer is not readily biodegradable. However, polymer in soil will undergo slow abiotic and biotic degradation processes forming small molecules of water, inorganic salts and oxides of nitrogen and carbon.

Based on the estimates above, the notified polymer is not expected to pose an unacceptable risk to the aquatic ecosystem from the reported use pattern.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

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 *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 by Bronson & Jacobs Pty Ltd regarding storage of the notified polymer:
  - *Store away from strong oxidising agents*
  - *Avoid exposure to heat, sources of ignition and open flame.*

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by 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 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;
  - the notified polymer is introduced in a solid, particulate form.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from viscosity increasing agent, thickener stabiliser and emulsion stabiliser for a range of cosmetic and personal care 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;
  - 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 provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.