File No PLC/776

24 July 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Acrylates/Stearyl Acrylate/Dimethicone Methacrylate Copolymer

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Avon Products Pty Ltd (ABN 48 008 428 457)
120 Old Pittwater Road
BROOKVALE NSW 2100

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, Import Volume.

NOTIFICATION IN OTHER COUNTRIES
Japan, Korea, China, Philippines, EU.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
KP-561, KP-561P

OTHER NAME(S)
Acrylates/Stearyl Acrylate/Dimethicone Methacrylate Copolymer

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >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:	Light yellow transparent solid
Melting Point/Glass Transition Temp	25-35°C
Density	Not determined
Water Solubility	No water solubility is expected based on the structure of the notified

	polymer.
Dissociation Constant	No dissociable functionality exists in the notified polymer.
Reactivity	Stable under normal environmental conditions. However, may be explosive or flammable when exposed to ignition sources.
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	<1	1	1	1	1

USE

The notified polymer will be used as a film-forming agent in finished cosmetic products such as lipstick at <20%.

Mode of Introduction and Disposal

Initially, the notified polymer will be imported as a component of finished cosmetic products such as lipstick at concentrations <20% in packages of 3, 5.5 and 6 g.

In future, the notified polymer may be imported at concentrations >60% and reformulated into finished cosmetic products.

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 the notified polymer or analogue chemical.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Rat, acute oral	LD50 >5000 mg/kg bw	no	OECD TG 401 equivalent
Rabbit, skin irritation	slightly irritating	yes	OECD TG 404 equivalent
Rabbit, eye irritation	slightly irritating	yes	OECD TG 405
Skin sensitisation - non-adjuvant test	no evidence of sensitisation	no	OECD TG 406 (Buehler test)
Bacterial reverse mutation test	non mutagenic	no	OECD TG 471

All results were indicative of low hazard.

Skin Irritation:

In the skin irritation test, the notified polymer showed irritant effects as evidenced by well-defined erythema in 3 out of 5 females and very slight erythema in 1 male. Very slight erythema persisted in 4 out of 5 females 72 hours after treatment. Very slight oedema was also observed in 3 out of 5 females but was no longer present at 72 hours. Based on these effects the notified polymer was considered mildly irritating but they were not sufficient for classification as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: (1008)2004].

Eye Irritation:

In the eye irritation test, the notified polymer showed irritant effects in the conjunctivae. Diffuse, crimson redness with individual vessels not easily discernible was observed in all animals tested, persisting as vessels definitely injected above normal for 7 days in 2 animals. Based on these effects the notified polymer was considered mildly irritating but they were not sufficient for classification as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: (1008)2004].

Occupational Health and Safety Risk Assessment

Raw ingredient for reformulation into cosmetic products

The notified polymer (>60%) is expected to be pre-heated to ensure it is in liquid form, then weighed and

pumped into mixing vessels. Dermal and ocular exposure may result from spills, drips and splashes during weighing and when connecting and disconnecting hoses to drums containing the notified polymer and the mixing vessel.

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

After mixing, packaging of cosmetic product containing the notified polymer (<20%) is expected to take place using automated filling equipment. 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 staff are expected to wear appropriate Personal Protective Equipment (PPE), including safety glasses and chemical resistant gloves to minimise the potential for exposure.

Component of finished cosmetic products
Dermal and ocular exposure during transport and handling is not likely except in the case of handling breached product packaging.

Beauticians may experience dermal and ocular exposure during application of various cosmetic products containing the notified polymer (<20%). 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 and the expectation that any product residues will be rinsed off.

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 skin or eye irritation as indicated by the tests supplied by the notifier.

Public Health Risk Assessment
The notified polymer will be in products such as lipstick and sold to the general public resulting in widespread public exposure. Exposure to the notified polymer will vary depending on individual use patterns. Typically, 0.01 g of lipstick containing <20% notified polymer is expected to be applied to the lips up to 4 times a day.

Although the public will be exposed to the notified polymer during use of cosmetic products such as lipstick, the risk to public health is not considered to be unacceptable given the proposed use patterns of the products and the low potential for skin and eye irritation of the notified polymer. In addition, the public may also ingest lipsticks containing the notified polymer (<20%). There are no repeat dose oral toxicity data on the notified polymer, however, based on its low acute hazard and low bioavailability, it is not expected to pose an unacceptable risk via the oral route.

7. ENVIRONMENTAL IMPLICATIONS

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

Environmental Risk Assessment
The Predicted Environmental Concentration (PEC) to rivers is calculated to be 0.63 µg/L, assuming 97% of the notified polymer being disposed of to the sewage system, which is in the worst scenario. However, polymers that meet PLC criteria are not considered a concern to the aquatic compartments. In addition, the majority of the notified polymer will end up with sludge in water treatment plants, and be disposed of to landfill. It is expected that 3% of the notified polymer will be directly disposed of to landfill.

Based on the reported use pattern, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment.

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.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containments, 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.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the notified polymer has changed from a film-forming agent for use in cosmetic products, or is likely to change significantly;

- the amount of notified polymer being introduced has increased from 1 tonne, or is likely to increase, significantly;
- if 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.

No additional secondary notification conditions are stipulated.

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.