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

FULL PUBLIC REPORT

Polyacrylate-13

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**Director
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FULL PUBLIC REPORT**Polyacrylate-13****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Bronson & Jacobs Pty Ltd (ABN 81 000 063 249)
 5 Parkview Drive
 Australia Centre
 Olympic Park NSW 2127

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, Concentration of polymer in product.

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(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2005)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polyacrylate-13
 SEPIPLUS 400 (aqueous mixture of polyacrylate-13, polyisobutene and polysorbate-20)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >10000

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

| <i>Criterion</i> | <i>Criterion met (yes/no/not applicable)</i> |
|--|--|
| 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 to opaque, white to pale yellow, emulsion (SEPIPLUS 400) |
| Glass Transition Temp | > 200°C. No glass transition temperature was observed below the decomposition temperature of 200°C. |
| Density | 100 kg/m ³ at 20°C (SEPIPLUS 400) |
| Water Solubility | Stated to be insoluble. Polymer is dispersible in water and forms a gel. |
| Dissociation Constant | The notified polymer contains a salt of a very strong acid, and therefore it is expected to remain dissociated throughout the environmental pH range of 4-9. |
| 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

| <i>Year</i> | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>5</i> |
|---------------|----------|----------|----------|----------|----------|
| <i>Tonnes</i> | 0.5 | 1 | 1 | 1 | 1 |

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported as a component of the product SEPIPLUS 400 in up to 70% concentration. This polymer emulsion will be transported in 30 kg polyethylene drums from the dock to a holding warehouse, and then to the customer by road.

Reformulation/manufacture processes

The notified polymer will not be manufactured in Australia. Reformulation will be carried out at several cosmetic manufacturing sites.

In a typical process, a compounder will weigh out the notified polymer manually into a separate container. This will then be manually added to a mixing tank, along with other ingredients. During the blending a chemist may take samples of the product containing the notified polymer using a dip tube. After the blending is complete a packer will supervise the use of a line filler and capper to transfer the finished product into the retail bottles. The packaged cosmetic products will then be stored and handled by a store person.

Use

The notified polymer (as a component of SEPIPLUS 400) is used as a thickener for cosmetic gels, creams and lotions at levels of up to 2%. Typical applications are:

- in skin gel-creams at levels of 1.0-1.5% notified polymer;
- in self-tanning light emulsions at levels of 0.5-1.0% notified polymer.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport and storage

Transport and warehousing workers are expected to have dermal and ocular contact with the notified polymer solution and products containing the notified polymer only in the event of accidental spillages.

Reformulation

Dermal and ocular exposure to the notified polymer solution (up to 70% polymer) may occur due to drips, spills and splashes during weighing out and manual addition to the blending tank. The compounder is expected to wear personal protective equipment such as glasses, gloves and coveralls. Dermal and ocular exposure to the polymer solutions may potentially occur during other processes involving the notified polymer such as sampling, cleaning, maintenance, or by accidental spills during the packing process. However, exposure to significant amounts of the notified polymer is limited because of the largely automated processes, and the engineering controls and personal protective equipment worn by workers.

Beauty Industry

Intermittent, wide-dispersive use with direct handling is expected to occur among cosmeticians and beauticians. According to EASE (1997) modelling of this work environment, dermal exposure in the range of 1-5 mg/cm²/day of products containing up to 2% of the notified polymer could result.

PUBLIC EXPOSURE

Since the notified polymer will be in products sold to the general public, widespread public exposure to the notified polymer at up to 2% concentration is expected. Exposure to the notified polymer will vary depending on individual use patterns. Typical use patterns for potential applications:

- 1.2 g of skin cream containing 1.0-1.5% notified polymer is applied to the hands/face once or twice a day;
- 8.0 g of self-tanning lotion containing 0.5-1.0% notified polymer is applied to the body once a day.

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 SEPIPLUS 400 (up to 70% notified polymer).

| <i>Endpoint</i> | <i>Result</i> | <i>Classified?</i> | <i>Effects Observed?</i> | <i>Test Guideline</i> |
|--|------------------------------------|--------------------|--------------------------|-----------------------|
| 1. Rat, acute oral | LD50 > 2000 mg/kg bw | no | no | OECD TG 423 |
| 2. Genotoxicity - bacterial reverse mutation | non mutagenic | no | no | OECD TG 471 |
| 3. Dermal irritation – human 48-hour occlusive single patch test | non irritating at 3% | no | yes | In house procedure |
| 4. Eye irritation – <i>in vitro</i> HET-CAM* test | non irritating at 3% | no | no | In house procedure |
| 5. Eye irritation – <i>in vitro</i> RBCA** method | non irritating at 5% | no | no | In house procedure |
| 6. Skin sensitisation – human repeat insult patch test | no evidence of sensitisation at 5% | no | yes | In house procedure |

* HET-CAM: Hen's egg test-chorio allantoic membrane.

** RBCA: Red blood cell aggregation

Dermal irritation

Very slight to slight erythema was observed in 2/20 human subjects following 48 hour exposure to the notified chemical. All effects had reversed by 48 hours after patch removal. Therefore SEPIPLUS 400 is not classified as an irritant.

Skin sensitisation

One subject (out of 49) showed slight erythema on days 5,8 and 10 of the induction phase and at the induction site immediately after challenge. No reactions were observed at the challenge site, therefore SEPIPLUS 400 did not induce any skin sensitisation; it was well tolerated.

Although the *in vitro* eye irritation tests and human patch tests are not validated for classification, the negative results in all tests indicate low hazard of the notified polymer solution.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Although exposure to the notified polymer could occur during reformulation processes such as weighing out, sampling or cleaning and maintenance, the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

PUBLIC HEALTH

Although the public will be exposed to the notified polymer during use of cosmetic products such as creams and lotions, the risk to public health is considered to be low due to the predicted low hazard of the notified polymer and the low concentration of the notified polymer in the products.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release to the environment may be considered at several stages:

1. Transport of the notified polymer prior to formulation. This is not likely to constitute a major hazard, as the material is likely to be containerised, or in packaging designed to withstand impact. Accidental spills during transportation should be relatively easily recovered and disposed of, as described under Environmental Emergency Procedures.
2. Storage and product formulation. With the relatively low level use proposed for this product and with its formulation and dispensing in closed systems, it is unlikely that there will be any significant release to the environment. Formulation of the product is a batch process with a batch typically 6 tonnes with each batch containing up to 120 kg of the notified chemical being produced in 4 hours, 16 batches per year. Emissions to waste water are possible while cleaning the equipment. It is estimated that 2-3% final product are rinsed into the waste water collection which then goes to a biological treatment plant. The treatment plant will be managed according to the requirements of Sydney Water or their equivalent.
3. End Use. Given the use pattern of the notified chemical, release is entirely expected to occur to the aquatic compartment. This release is expected to be relatively diffuse. A small amount of the notified polymer (<1.0%) will remain in containers and will be disposed of to land-fill via normal household rubbish collection.

ENVIRONMENTAL FATE

The majority of the total volume of notified polymer will be disposed of to sewer. In the sewage treatment plant, the notified polymer may end up in receiving waters or it may associate with sludge where it could be incinerated or be applied to agricultural land. The nature of creams and lotions indicates they could associate with sludge due to hydrophobic moieties or remain in solution due to hydrophilic moieties. Notified polymer that remains in the aquatic compartment is expected to eventually degrade via biotic and abiotic means. Similarly, notified polymer that is disposed of to agricultural land or to landfill is also expected to eventually degrade via biotic and abiotic means. The notified polymer should be relatively immobile and associate with soil and sediment, due to its very large molecular weight and net anionic charge. Notified polymer that is disposed of by incineration is expected to thermally degrade to form simple oxides of carbon, nitrogen, sulphur and sodium as well as water vapour.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. 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.

7.3. Environmental Risk Assessment

Since most of the polymer will be washed into the sewer, under a worst case scenario with no removal of the notified polymer in the sewerage treatment plant, the resultant predicted environmental concentration in sewerage effluent on a nationwide basis is calculated as follows:

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|--------|--------------|
| Annual quantity of chemical released to sewer | 1,000 | kg/year |
| Days per year where release occurs | 365 | days/year |
| Daily chemical release: | 2.74 | kg/day |
| Water use | 200.0 | L/person/day |
| Population of Australia (Millions) | 20.496 | million |
| Daily effluent production: | 4,099 | ML |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River: | 0.67 | µg/L |
| PEC - Ocean: | 0.07 | µg/L |

As ecotoxicity data were not provided, it is not possible to determine a Predicted No-Effect Concentration nor subsequently a Risk Quotient. However, given the diffuse release pattern, the notified polymer is not expected to pose an unacceptable risk to the environment, given the qualitative aquatic toxicity discussed above.

8. CONCLUSIONS**8.1. Level of Concern for Occupational Health and Safety**

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is No Significant Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. 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.

Disposal

- The notified polymer should be disposed of by thermal decomposition in an incinerator or to landfill.

Emergency procedures

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

10.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 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 subsection 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.