

File No: LTD/1075

27 May 2003

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

FULL PUBLIC REPORT

Keravis

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**Keravis****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Croda Singapore Pte Ltd (trading as Croda Australia) of Suite A1, 44-46 Mandarin Street VILLAWOOD NSW 2163 (ABN 34 088 345 457).

NOTIFICATION CATEGORY

Limited-small volume: Polymer with NAMW > 1000 (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular formula, structural formula, molecular weight, polymer constituents, residual monomers and impurities.

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)

No.

NOTIFICATION IN OTHER COUNTRIES

No.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Keravis (23% active ingredient)

MOLECULAR WEIGHT

NAMW likely to be >1 000

3. COMPOSITION

DEGREE OF PURITY

>60%

4. INTRODUCTION AND USE INFORMATION

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

Import.

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>	<1	<1	<1	<1	<1

USE

The notified polymer will be used in hair care products such as shampoos and conditioners at concentration of 0.23% notified polymer.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY

Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS

Croda Australia

TRANSPORTATION AND PACKAGING

The notified polymer is not manufactured in Australia, but will be imported as a raw material for formulation into hair care products. The notified polymer, imported as a 23% aqueous solution in 25 kg plastic drums, will be transported direct from the dockyards to the formulation site. The packaging for the finished products is 300 mL to 2.0 L plastic bottles.

5.2. Operation Description

The notified polymer will be imported and sold to formulators in the cosmetic industry for local manufacture of hair care products. Since Keravis has not been promoted and marketed in Australia, no formulators have been confirmed at this stage. Thus, details on the operation description cannot be supplied. A generic description of the formulation process is described below.

The hair care products are formulated in batch sizes of 2 000 kg. The notified polymer is poured manually into a stainless steel premixing vessel container and mixed with other ingredients. The resulting mixture is transferred under vacuum into a second sealed blending vessel where other components of the hair care products are added. Prior to packaging, sampling and quality testing of the preparation is carried out in the laboratory. The formulated hair care products will then be transferred to a filling machine with a multiple filling head and automatically poured into plastic bottles (300 ml to 2 L). The finished hair care products will contain 0.23% notified polymer. The bottled products will be packed in cardboard cartons and will be sent to a warehouse for storage until distribution to hairdressing salons and retail outlets.

Hairdressers will apply the hair care products containing the notified polymer at 0.23%. The product will be applied to hair for less than 5 min and then completely washed off after application.

5.3. Occupational exposure

Number and Category of Workers

<i>Category of Worker</i>	<i>Exposed To</i>	<i>Number</i>	<i>Exposure Duration (hour/day)</i>	<i>Exposure Frequency (day/year)</i>
Transport and Warehouse Workers	23% polymer aq. solution	<10	1-2	2-4
Manufacturing Operators	23% polymer aq. solution 0.23% polymer in finished products	>40	8	20
Quality control	23% polymer aq. solution 0.23% polymer in finished products	2	0.5	20
Salon workers	0.23% polymer in finished products	>1000	8-12	300
Retail workers	0.23% polymer in finished products	>1000	8-12	300

Exposure Details

<i>Category of Workers</i>	<i>Exposure Route</i>	<i>Exposure details</i>	<i>Controls</i>
Transport and Warehouse Workers	Dermal	Workers will handle sealed packages. Exposure is only expected in the unlikely event of an accidental spill	No PPE is recommended
Manufacturing Operators	Dermal, inhalation and ocular	Dermal and limited ocular exposure when opening and closing drums, adding the notified polymer manually into mixing vessel, and connecting and disconnecting transfer and filling lines. Dermal exposure due to drips and spills and if containers are overfilled at the filling station can also occur. Skin exposure may also occur during maintenance and when cleaning equipment.	Mixing vessels are enclosed. Filling machines are automated and fitted with local exhaust ventilation to capture any volatile or aerosol materials at the source. PPE includes overalls, safety glasses and/or safety shoes, PVC or disposable latex gloves and head cover.
Quality Control	Dermal and ocular	Limited dermal exposure to small quantities during sampling and testing.	PPE includes laboratory coat, safety glasses and rubber gloves
Salon workers	Dermal and ocular	Limited dermal and ocular exposure when applying hair care products.	No PPE is recommended
Retail workers	Dermal	Limited dermal exposure from damaged and leaking packages.	No PPE is recommended

5.4. Release

RELEASE OF CHEMICAL AT SITE

It is expected that up to 10 kg per annum of the notified polymer will remain in the empty import containers and will be disposed of in landfill. Release to the environment during reformulation and cleaning processes is expected to be small as closed, automated systems are used, and will total less than 20 kg per annum of the notified polymer. Wastewater resulting from the cleaning of formulation equipment will be passed through interceptor pits prior to release to sewer. Solid wastes collected from these pits will be disposed to landfill.

RELEASE OF CHEMICAL FROM USE

Since the notified polymer will be used in hair care products, majority of the import volume or up to 920 kg per annum is expected to be released to sewer. It is expected that up to 50 kg per annum of the notified polymer will be disposed of to landfill in empty product containers.

5.5. Disposal

The majority of the notified polymer will ultimately be disposed of to sewer. Spilt material will be contained by absorbent, placed into containers and disposed in landfill.

5.6. Public exposure

Public exposure through importation, transportation or storage is negligible. The notified polymer will be a component of hair care products, which is intended for professional hair salon market. However, the products will also be available to the public from hair salons, hence public exposure of the notified polymer is expected.

6. PHYSICAL AND CHEMICAL PROPERTIES

The following physical and chemical properties are determined from Keravis containing 23% notified polymer.

Appearance at 20°C and 101.3 kPa	Clear Liquid
Melting Point/Freezing Point	Not determined
Density	Approximately 1 000 kg/m ³
Remarks	No study report was provided.
Vapour Pressure	Negligible at ambient temperatures.
Remarks	No study report was provided.
Water Solubility	Not determined
Remarks	On the basis that the notified polymer is imported as a 23% aqueous solution, the water solubility is at least 230 g/L. By analogy with similar silicone polymers, the notifier indicates that the notified polymer is highly soluble in water above pH ~5.5. However, below this pH, the notified polymer is expected to exhibit limited solubility.
Hydrolysis as a Function of pH	Not determined
Remarks	The notified polymer contains peptides that may hydrolyse but are expected to remain intact over the environmental pH range.
Partition Coefficient (n-octanol/water)	Not determined
Remarks	Due to the notified polymer's expected high water solubility it is likely to partition into the aqueous phase.
Adsorption/Desorption	Not determined
Remarks	Based on the notified polymer's high water solubility it will have little affinity for organic matter in the soil and will, as a consequence, be mobile in both terrestrial and aquatic compartments. It is not clear whether the notified polymer exhibits surface activity that would cause it to absorb more strongly to soil.
Dissociation Constant	Not determined
Remarks	The peptide moiety of the notified polymer contains carboxylic acid side chains which can undergo dissociation.
Particle Size	Not determined.
Remarks	The polymer is imported as components of a liquid product.
Flash Point	>100°C
Remarks	From the MSDS for Keravis.
Flammability Limits	Not flammable
Remarks	No study report was provided.
Autoignition Temperature	Does not undergo autoignition.
Remarks	No study report was provided.

Explosive Properties

Not explosive

Remarks No study report was provided.

Reactivity

Stable under normal use conditions.

Remarks Under normal conditions of storage, the polymer is not expected to undergo degradation.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicological data were submitted

8. ENVIRONMENT**8.1. Environmental fate**

No environmental fate data were submitted

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT**9.1. Environment****9.1.1. Environment – exposure assessment***Exposure*

During formulation of the hair care products the notifier estimates that up to 20 kg per annum of notified polymer will be released into the environment as a result of spills and equipment cleaning. Subsequent water washes will pass to interceptor pits where the settled material will be collected and disposed of in landfill. Treated wastewater will be released to sewer.

The plastic import drums containing residual notified polymer (up to 10 kg per annum) will be disposed of to landfill. The bottles in which the hair product will be sold to consumers and the residues they contain (up to 20 kg per annum) will be disposed of in domestic landfill.

The majority of the notified polymer will be incorporated into hair products and as such will almost completely be released to the environment.

Fate

The notified polymer is highly soluble in water. However, it is expected this solubility decreases rapidly under acidic conditions. Therefore in landfill, the notified polymer has the potential to be mobile in both terrestrial and aquatic compartments. However, over time it is expected to adsorb to soil and sediments and degrade slowly through biotic and abiotic processes to give water and oxides of carbon, nitrogen and silicon.

The majority of the notified polymer will be released into the sewer following washing of hair. However, this will be in dilute manner as the notified polymer contained within these products will be released from domestic use at low concentrations. Over time the notified polymer is expected to adsorb to soil and sediments and degrade slowly by the processes described above.

9.1.2. Environment – effects assessment

No ecotoxicity data were submitted.

9.1.3. Environment – risk characterisation

The intended use pattern of the notified polymer expected to result in the majority of the chemical being eventually released to the environment. However, this will be in dilute manner as the notified polymer contained within the hair care products will be released from domestic use at low concentrations.

In a worst case based on maximum annual imports of 1 tonne per annum, all of which is released to sewer and assuming that none is removed during sewage treatment processes, and assuming a national population of 19,500,000 with each person contributing an average 200 L/day to overall sewage flows, the predicted concentration for release to ocean and river on a nationwide basis are 0.07 and 0.71 µg/L, respectively.

Amount of entering sewer annually	1000 kg
Population of Australia	19.5 million
Amount of water used per person per day	200 L
Number of days in a year	365
Estimated PEC _{Ocean}	0.07 µg/L (0.07 ppb)
Estimated PEC _{River}	0.71 µg/L (0.71 ppb)

In landfill the notified polymer has the potential to be mobile in both terrestrial and aquatic compartments. However, over time it is expected to adsorb to soil and sediments and degrade slowly through biotic and abiotic processes to give water and oxides of carbon, nitrogen and silicon.

The notified polymer's high water solubility indicates its potential to bioaccumulate will be low (Connell 1990).

Therefore, the environmental exposure and overall environmental hazard from the notified polymer is expected to be acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Reformulation will be carried out predominantly in closed systems, however addition of the polymer solution involves manual operations. Limited dermal and ocular exposure to the notified polymer is possible when opening and closing drums, connecting and disconnecting transfer and filling lines, and cleaning and maintenance of equipment. Limited dermal exposure to small quantities of the notified polymer during quality control testing can also occur. The use of ventilation systems and personal protective equipment such as overalls, gloves, protective foot wear and protective glasses would limit exposure to the notified polymer during the above activities.

Intermittent dermal exposure can occur for hairdressers applying the hair care products to the hair. However, the low concentration of the notified polymer in the hair care products (maximum 0.23%) would ensure low exposure.

Except in the event of accident, exposure during transport and storage is limited, since workers are only expected to handle sealed containers.

9.2.2. Public health – exposure assessment

In home use, typical shampoo use is expected to be 12 grams per application, 2 to 7 times per week. The expected absorption is <10%. At 0.23% notified polymer, the consumer would be exposed to 2.76 mg of notified polymer per day (expected to be 0.046 mg/kg/day for a 60 kg female).

9.2.3. Human health - effects assessment

The notified polymer is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The MSDS for the

aqueous solution of the notified polymer indicates that the polymer may be a slight skin irritant. The label indicates that the polymer solution may be a slight eye irritant.

9.2.4. Occupational health and safety – risk characterisation

The notified polymer is of low concern to occupational health and safety. The control measures in place during hair care product manufacture and the use of protective equipment when handling the notified polymer will minimise the risk of adverse health effects. No specific risk reduction measures are necessary.

The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

9.2.5. Public health – risk characterisation

Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer. Although the notified polymer may be a slight eye irritant based on a similar product, it is present at a very low concentration in the formulated product, and it is normal practice to minimise eye contact with shampoos. Therefore, the notified polymer is not expected to pose a health risk to the public.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

The notified polymer is not considered to pose a risk to the environment based on its low import volume.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Low Concern to public health under the conditions of the settings described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Exhaust ventilation during hair care product manufacture and filling operations
 - Enclosed and automated mixing and bottle filling operations
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid spills and splashes during manual transfer of the polymer into the mixing vessel and during cleaning operations
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Overalls (or similar protective apparel)
 - Safety glasses
 - Safety footwear
 - Impervious gloves

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 end users to minimise environmental exposure during use of the notified polymer:
 - Do not allow material or contaminated packaging resulting from spills to enter drains, sewers or water courses.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Gross spills/release of the notified polymer should be contained by sand or inert powder and earth. Collect and seal in properly labelled drums for disposal in landfill.

12.1. 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:
 - The import volume increases above 1000 kg per annum, the notifier should provide results and test reports for vapour pressure, adsorption/desorption, hydrolysis as a function of pH and aquatic ecotoxicity data for fish, Daphnia and algae for the notified polymer.
- (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.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: Connell DW ed. Bioaccumulation of xenobiotic compounds. Boca Raton, USA, CRC Press, pp 47-57.

NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1994b) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. National Occupational Health and Safety Commission, Canberra, AusInfo.