File No SAPLC/47

July 2006

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Acudyne SCP

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 the Environment and Heritage has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rohm and Haas Australia Pty. Ltd (ABN 29 004 513 188)
4th Floor, 969 Burke Road, Camberwell, VIC. 3124

NOTIFICATION CATEGORY
Self Assessment: Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, Details of Import Volume.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada 2005, Schedule VI Polymer of Low Concern

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Acudyne SCP

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains only low concern functional groups

MOLECULAR WEIGHT
> 10, 000

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
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	Clear, colourless to pale yellow liquid as supplied in a solution in water.
Melting Point/Glass Transition Temp	Not applicable because the polymer is not isolated from solution.
Specific Gravity	Approximately 1.1 as a 24% w/w solution of the notified polymer in water.
Water Solubility	The polymer is readily soluble
Dissociation Constant	The notified polymer has an anionic group expected to have typical acidity.
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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	Up to 1	Up to 3	Up to 3	Up to 3	Up to 3

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will not be manufactured in Australia.

The notified polymer will be imported either as a component (1-2% concentration) of ready to use packaged hairstyling products (non-spray) for retail sale or as a component of Acudyne SCP product (24% concentration) in water for reformulation of hairstyling products in Australia.

Currently no end customers have been established for importation of the notified polymer in either form. However, it is expected that up to 3 customers in Melbourne and a further 3 in Sydney will be identified.

The packaged hairstyling product (containin the notified polymer) in 200 to 300 gram plastic containers will be transported from the wharf by road to the importer's warehouse for storage under cover until sold and thereafter transferred by road to various retail outlets throughout Australia.

The imported product, Acudyne SCP (containing the notified polymer) will be imported in 200 litre steel drums. The drums will be transported from the wharf by road to the importer's warehouse for storage under cover in a bunded area until sold and thereafter transferred by road to the reformulator's site where it will be stored in a bunded area until reformulated into hairstyling products.

Reformulation processes

During reformulation, the notified polymer will be manually weighed and then transferred using a mechanical drum lifter to a stainless steel mixing vessel. Once combined with other ingredients and blended into the finished hairstyling product, it will be pumped into a holding tank prior to packing into retail containers. The finished hairstyling product will be packaged into 200 to 300 gram plastic containers via an automated packaging line. The packaged containers will be packed in quantities of 10 to 20 per cardboard box prior to sale to retailers.

Use

The notified polymer will be used as a component of hair styling products for salon and home use.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport and Storage

Transport and warehousing workers may come into dermal and ocular contact with the notified polymer through accidental leaks and spillages of the drums and containers.

Reformulation

During reformulation, worker exposure to the notified polymer may occur by either dermal or by accidental ocular routes. Workers will wear impermeable gloves, eye protection and coveralls. However significant exposure will be limited due to the workplace practices and personal protective equipment used.

Worker exposure to the notified polymer (1-2% notified polymer) can occur during filling line operation for finished product and cleaning automated filling equipment. Filling line workers will wear impermeable gloves, eye protection and coveralls. Possible routes are via:dermal or ocular routes. However significant exposure will be limited due to the workplace practices and personal protective equipment used.

End-use in hairdressing salons

Intermittent dermal exposure to hairdressers is likely to occur when applying the hair care products to the hair of customers in salons, as gloves will probably not be used for this process. Inhalation exposure is not expected as the products will not be sprayed. Repeated exposure may occur through use of the product on different customers. Approximately 5g of hairstyling product, containing 0.1g of notified polymer will be applied to each customers. Some accidental ocular exposure may occur. Inhalation exposure is not expected. The low concentration of the notified chemical in the hair care products (1-2%) will reduce the exposure of hairdressers.

PUBLIC EXPOSURE

The Acudyne SCP product will not be sold directly to the public. However, it is expected that members of the public will use approximately 90% of the hairstyling product containing 1-2% of the notified polymer.

Public exposure to the notified polymer will be by either dermal or ocular routes. The products will not be applied by spraying. The vast majority will be dermal exposure due to the hairstyling product remaining in users' hair until such time that it is washed out.

Approximately 5g of hairstyling product, containing 0.1g of notified polymer, will be applied per application and may remain in users' hair for up to 24 hours.

Public exposure during transport and storage is unlikely unless the packaging is accidentally breached.

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..

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 >5,000 mg/kg bw	no	no	OECD TG 425
2. Rat, acute dermal	LD50 >5,000 mg/kg bw	no	no	OECD TG 402
3. Rabbit, skin irritation	non-irritating	no	yes	OECD TG 404
4. Rabbit, eye irritation	non-irritating	no	yes	OECD TG 405

5. Skin sensitisation – Human Repeated Insult Patch Study	no evidence of sensitisation.	no	no	
6. Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	OECD TG 471

All results were indicative of low hazard.

Skin Irritation
A primary skin irritation test was conducted with rabbits to determine the potential for the notified polymer to produce irritation after a single topical application. One hour after patch removal, all subjects exhibited very slight to well-defined erythema and very slight oedema. All animals were free of dermal irritation by 48 hours. The Primary Irritation Index (PII) according to Draize score was 1.2.

Eye Irritation
A primary eye irritation test was conducted with rabbits to determine the potential for the notified polymer to produce irritation after a single instillation via the ocular route.

No corneal opacity or iritis was noted for any treated eye during the study. Approximately one hour after instillation, conjunctivitis was observed in all treated eyes. All animals were free of ocular irritation by 48 hours.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY
Worker exposure at the formulation plant to the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers. The notified polymer is of a high molecular weight and is present in the product at a relatively low concentration, reducing potential exposure to salon workers. Toxicological information provided by the notifier indicates that the notified polymer is non-hazardous.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on low hazard as well as the engineering controls and personal protective equipment used by workers.

PUBLIC HEALTH
As the notified polymer will be used in hairstyle products which are available throughout Australia in small containers, public exposure is expected to be widespread. Dermal and accidental eye contact is expected to be likely the main route of exposure. However, given the small amounts used per application, having large molecular weight therefore unlikely to cross biological membranes, the expected low toxicity and the low concentration of the polymer in the product, the public risk is expected to be low.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks of the drums or steel packaged containers.

During formulation and packaging, spills are expected to be minimal. When spills occur, they will be contained by bunding, collected with absorbent material and sent to a licensed off site waste disposal centre. Empty drums from import will be sent to drum reconditioners.

Cleaning of manufacturing and packaging equipment will be performed by flushing with water. Cleaning water and product residues will be transferred to the on site waste paint treatment facility where solids will be precipitated and later disposed of to a licensed waste landfill site.

The total amount of waste polymer produced during reformulation and packaging due to spills, drum residues and cleaning is expected to be approximately 3% or up to 90 kg of the maximum import volume.

Approximately 5% or 150kg of the notified polymer will remain as residues in consumer packaging and will be disposed of to landfill via domestic waste.

The vast majority (up to 2700 kg) of the notified polymer will be released to sewerage systems throughout Australia through washing of hair.

ENVIRONMENTAL FATE

The notified polymer is expected to be hydrolytically stable and to not be readily biodegradable. Due to its high molecular weight and hence inability to cross biological membranes, the notified polymer is not expected to bioaccumulate.

The notified polymer is readily soluble in water and will initially be mobile in aquatic and terrestrial compartments. However, due to its anionic nature, the notified chemical is likely to be immobilised via adsorption onto soil particles and sediments in landfill and sewage treatment plants, eventually degrading through biotic and abiotic processes to form oxides of carbon, nitrogen and sulphur.

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 over-chelation of the nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This may 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.

Due to its molecular weight and nature, the notified polymer is not likely to bioaccumulate.

7.3. Environmental Risk Assessment

All of the imported notified polymer will eventually be released into the environment. Up to 240kg will be released to landfill via spills, cleaning equipment and packaging residues.
The remainder, or up to 2760 kg, will be discharged into sewerage systems after washing hair.

The following worst-case scenario was used to determine the predicted environmental concentrations (PECs) in the aquatic environment for the notified polymer.

Assuming that 90% of the notified polymer is eventually released to the sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is 7.4kg/day using the maximum import volume of 3 tonnes/annum.

Based on a national population of 20 million and a daily water consumption of 200 litres/day the Predicted Environmental Concentration (PEC) is calculated as follows:

$$PEC_{sewer} = \frac{(2{,}700 \times 1 \times 10^6)\ mg}{20{,}000{,}000 \times 200 \times 365\ L}$$
$$= 0.00185\ mg/L$$
$$= 1.85\ \mu g/L$$

Although it is expected that some of the notified polymer will be adsorbed onto sewage plant sediments, and discharge from sewage treatment plants will be further diluted when released to inland and ocean waters, the above PEC can be taken as a worst case scenario.

Based on the proposed use pattern, the release of the notified polymer is unlikely to exist at levels that could pose a threat to aquatic organisms. Further, The high molecular weight and water solubility indicate a low potential to bioaccumulate.

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.

- Employers should ensure that the following personal protective equipment is used by plant operators and quality assurance staff to minimise occupational exposure to the polymer:
  - Coveralls;
  - Protective gloves;
  - Safety goggles; and
  - Safety boots.

  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 the reformulator to minimise environmental exposure during reformulation of the notified polymer:
  - Bunding

Disposal

- Spillages and container residues containing notified polymer should be disposed of to landfill and/or liquid waste treated on-site or collected by licensed waste contractors for treatment at authorised waste treatment plants.

Storage

- The following precautions should be taken by the importer and reformulators regarding storage of the notified polymer:
  - Bunding

Emergency procedures

- Spills/release of the notified polymer should not be flushed into sewers or waterways. Spills should be taken up with absorbent material and disposed of to a licensed waste landfill site.

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.