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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer W 37194

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Schwarzkopf Pty Ltd of 20 Rodborough Rd, Frenchs Forest, NSW (ABN 21 000 076 782)

NOTIFICATION CATEGORY
Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Names
CAS Number
Molecular Formula
Structural Formula
Spectral Data
Hazardous Impurities/Residual Monomers
Additives and Adjuvants
Polymer Composition
Manufacture/Import Volume

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
USA, PMN (1988)

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Acrylamidopropropyl trimonium chloride/acrylates copolymer

MARKETING NAME(S)
Polymer W 37194 (23 % polymer in aqueous solution)

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD: Infrared spectroscopy

3. COMPOSITION

DEGREE OF PURITY
93.5 % Molecular weight determination by gel permeation chromatography shows low molecular weight species of 6.5 % MW < 1000. These are unknown polymeric impurities.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

None present at above the relevant cutoffs for classification of the notified polymer as a hazardous substance.

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

Chemical Name	Unspecified polymeric impurities		
CAS No.		*Weight %*	6.5

DEGRADATION PRODUCTS
None known.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer will in imported as an aqueous solution. All of the residual monomer content is available for release.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. It will be imported as a component of hair conditioner and lotion as part of a hair dye kit. The kit will be used in hair salons and in the consumer market.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
A quantity in the range of 1 – 3 tonnes per annum will be imported for each of the first five years.

USE
The notified polymer is an anti-static agent, film former and hair fixative. It will be used as a component of hair lotion (0.5 % polymer) which is applied prior to hair dying and in a conditioner (3.75 % polymer), which is used after hair dying.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Sydney, NSW

IDENTITY OF MANUFACTURER/RECIPIENTS
Schwarzkopf Pty Ltd
20 Rodborough Rd, Frenchs Forest NSW 2086

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component of hair lotion (15 mL plastic bottle) and hair conditioner (50 mL plastic bottle) within a hair dye kit. The packaged goods will be transported by road from the wharf to the notifiers warehouse where it will be stored prior to distribution by road to retail and hair salon outlets.

5.2. Operation Description

End-use
The imported hair dye kit will be sold to both retail and salon markets. The lotion in each kit is intended for single use per dye application, while the conditioner is intended for multiple uses between hair dye applications.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and warehousing	10	1-2 hr	20 days/year

Retail workers	5000	0.5 hr	100 days/year
Salon workers	1000	0.5 hr	200 days/year

Exposure Details
Waterside, transport and warehouse workers will only handle the imported product packed in boxes. Exposure is only likely to occur in the event of a spill from damaged containers.

Supermarket workers will unpack the boxes and place the shampoo containers on supermarket shelves. Exposure is only likely to occur in the event of a spill from damaged containers.

Salon workers will open the hair dye kit, remove and open the bottles of lotion or conditioner. They will pour a small amount of the lotion (15 mL) or conditioners (50 mL) into their hands and apply it to the customers hair by massaging thought the hair with their hands. The MSDS recommends that the supplied gloves be worn when using the dye kit. The hair is then rinsed into the basin and dried with a towel.

5.4. Release

RELEASE OF CHEMICAL AT SITE
No manufacture or reformulation will take place in Australia.

RELEASE OF CHEMICAL FROM USE
The majority of the notified polymer will be incorporated into hair care products and as such will almost completely be released to the environment. The notifier indicates that approximately 90 % of the import volume of the notified polymer will be released to sewer and the remaining 10 % will be disposed of to landfill as residue in import containers. Thus, based on the maximum import volume, 2700 kg/year of the notified polymer will be released to sewer and 300 kg/year in landfill.

The notifier has provided a predicted concentration in receiving waters. Assuming the average wastewater discharged to the sewer in Australia is approximately 190 L/person/day and that the population of Australia is approximately 19 million, the wastewater discharged to the sewer is approximately 3610 ML/day. Therefore, the PEC can be calculated as follows:

PEC = 2700/365/3610 = 0.002 ppm.

Point source estimate
Based on use of the conditioner which contains 3.75 % notified polymer, and 10 g being used per application, the amount of polymer per application is 375 mg.

The average water usage in a shower is assumed to be approximately 60 L based on US EPA exposure estimates. Therefore, 6.25 mg/L (ppm) of the notified polymer will be released to sewer for each use.

The PEC in metropolitan and rural areas are estimated to be 0.00625 ppm (1:1000 dilution) and 0.156 ppm (1:40 dilution) respectively.

5.5. Disposal
The notified polymer will ultimately be disposed of in either the sewer (major proportion) or landfill. Residues in empty containers will be disposed of to landfill via household garbage collection.

5.6. Public exposure
The imported product will typically be applied by adult consumers (general public) to wet hair during showering. People generally keep their eyes closed during showering to avoid contact with eyes. The public will be exposed to the notified polymer at a concentration of 0.5 % (lotion) or 3.75 % (conditioner). Exposure to the lotion will only occur on occasions where the hair is dyed, while exposure to the conditioner will be regular (2 to 7 times per week).

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Solid; imported only in aqueous solution.

Melting Point/Freezing Point Not determined

Remarks Notified polymer is not isolated from aqueous solution.

Density Approximately 1000 kg/m^3 at 25ºC

Remarks Aqueous solution.

Vapour Pressure Not determined.

Remarks The high molecular weight and ionic nature of the notified polymer will result in a negligible vapour pressure.

Water Solubility > 230 g/L at 20ºC

Remarks The notified polymer is produced as a solution containing the polymer in water at a concentration of 230 g/L. Therefore, its solubility in water is expected to be at least 230 g/L.

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer contains an amide linkage that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis is unlikely to occur.

Partition Coefficient (n-octanol/water) Not determined

Remarks The high expected water solubility of the notified polymer is indicative of partitioning mainly into the aqueous phase.

Adsorption/Desorption Not determined

Remarks The notified polymer is water-soluble and is potentially mobile in both aquatic and terrestrial compartments. However as a consequence of its cationic nature, the notified polymer is expected to associate with the soil matrix and sediments and as such will be immobile in soil.

Dissociation Constant Not determined

Remarks The notified polymer is expected to remain fully dissociated due to the quaternary ammonium group. The notified polymer also contains carboxyl groups which are expected to have a pKa value of 3-5.

Flash Point

Remarks Not flammable (aqueous solution)

Flammability Limits

Remarks Not flammable (aqueous solution)

Autoignition Temperature

Remarks Will not autoignite (aqueous solution)

Explosive Properties

Remarks Not expected to be explosive on structural grounds.

Reactivity

Remarks The notified polymer is stable under normal use conditions.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicity data were submitted.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.1.2. Bioaccumulation

Data regarding the bioaccumulation potential of the notified polymer were not provided for this notification. The notified polymer's expected high water solubility suggests that there is low potential for bioaccumulation (Connell 1990).

8.2. Ecotoxicological investigations

No ecotoxicity data specific to the notified polymer were submitted. However, the notifier has included a literature reference that discusses the toxicity of a variety of cationic polymers to aquatic organisms (Biesinger and Stokes, 1986). While this provides a general indication of the toxicity of these compounds to selected aquatic organisms, it is difficult to draw conclusions with respect to the toxicity of the notified substance as the structures of the polymers discussed were not provided. Nonetheless, the results outlined in this paper are discussed below.

A total of 15 cationic polymers were tested on various aquatic species including fish (fathead minnows), daphnids, gammarids and midges. In addition, the paper describes a microcosm study where one of these polymers was tested using five aquatic animals (no fish) and 10 algal species.

In the actue bioassay experiments toxicity to daphnids and fish ranged from < 1 ppm to > 100 ppm. The results indicating highest toxicity were a 48 h EC50 = 0.09 ppm to *Daphnia magna* (polymer K) and a 96 h LC50 = 0.88 ppm to fathead minnow (polymer E).

Acute toxicity testing on algae was not performed. However, 10 algal species were included in the microcosm study where polymer E (highly toxic to fish with a 96 h EC50 = 0.88 ppm) was tested at concentrations of 1.34, 13.4 and 31 ppm. In these tests, total number of algae for the latter two concentrations peaked at a later time than in the control. In the high concentration test, the number of algae increased slowly at first and the authors state many of the algae were probably flocked by the polyelectrolyte. However, algae numbers were very high by Day 48. This is possibly because the daphnid numbers were low with reinoculated daphnids not living until after day 40 when they started to multiply and crop the algae.

Algal species composition differed among treatment groups because of the interaction of several factors including indirect factors induced by changes in animal numbers and species. On day 48, species diversity was normal in the lower two concentrations compared to the controls. However, in the highest concentration, *Scenedesmus* comprised 98 % of the algae.

It is concluded from the microcosm study that algal growth was delayed at the higher concentrations with algal cells possibly bound by the polymer and unable to reproduce. It was not evident that the polymer caused a direct toxic effect on the algae.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Exposure

The intended use pattern is expected to result in the majority of the notified polymer being eventually released to the aquatic 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. The notified polymer is expected to eventually partition to soil/sediment and slowly degrade through biological and abiotic processes to water and oxides of carbon and nitrogen.

A non-point source PEC in receiving waters of 2 μg/L (ppb) was derived in Section 5.4. This calculation has been re-done using slightly different assumptions as follows:

100 % release to sewer (ie, 3000 kg per annum or 8.2 kg per day);
Total population of 19 million people using 200 L/day of water[1] totalling 3800 ML/day.

These assumptions result in an expected concentration in effluent of 2.2 ppb.
When released to receiving waters, a dilution factor is considered. This factor can be highly variable. In some cases, dilution may not occur (eg, dry riverbeds in summer) while other cases, dilution will be very high (eg, effluent release into the ocean). For consumer products, an average dilution factor for sewage from treatment plants of 10 is assumed. Applying this results in a Predicted Environmental Concentration (PEC) around 0.22 ppb. This concentration is expected to be lower as a result of removal from the aquatic compartment through association between the notified polymer and dissolved organic carbon.

Fate

After release to the aquatic compartment, the notified polymer is expected to eventually partition to soil/sediment and slowly degrade through biological and abiotic processes to water and oxides of carbon and nitrogen. In landfill, the notified polymer is also expected to associate with the soil matrix and slowly decompose by the processes described above.

9.1.2. Environment – effects assessment

No results for the notified polymer have been provided although Section 8.2 summarises a paper provided with the notification on toxicity of various cationic polymers to aquatic organisms. In addition to this, other information indicates the cationic polymers may be highly toxic to aquatic species. For example, Boethling and Nabholz (1997) state 'Cationic polymers of concern for aquatic toxicity include polymers that contain a net positively charged atom or that contain groups that can reasonably be anticipated to become cationic in water.' These authors also supply a list of toxicities associated with representative polymers containing amino nitrogen. Typical toxicities towards fish for polymers containing approximately 6 % amino nitrogen (as does the present polymer) range between 0.15-0.76 mg/L.

As indicated by Nabholz (1993) algae are likely to be up to six times more sensitive to this class of polymer than fish. Therefore, for the purposes of calculating a PNEC, a 72-hour EC50 of 0.025 mg/L will be used.

A predicted no effects concentration (PNEC) can be determined when at least one acute EC50 for each of the three trophic levels is available (ie. fish, invertebrates, algae). The PNEC is calculated by taking the EC50 value of the most sensitive species, and dividing this value by an assessment safety factor of 100 as there is an indication of toxicity for three trophic levels. Using a worst case scenario safety factor of 100, the PNEC is 0.25 μg/L.

9.1.3. Environment – risk characterisation

The notified polymer will be used in shampoos and most will eventually be released into domestic sewage systems as a consequence of product use. It has a high water solubility (230 g/L), indicating that it will potentially be mobile in both aquatic and terrestrial compartments. However as a consequence of its cationic nature, the notified polymer is expected to associate with the soil matrix and sediments where it is expected to degrade to water and

[1] An average daily water use of 150 L is usually used to determine a worst case scenario. However, this may be too conservative. The latest European guidance indicates 200 L/person/day is more likely, and this is supported in Australia where Australian Bureau of Statistics figures suggest water use even higher than this. Therefore, a value of 200 L/person/day has been used.

oxides of carbon and nitrogen through biological processes.

The PEC/PNEC ratio for the aquatic environment, assuming nationwide use, is 0.9. This value is less than (although approaching) 1, indicating an acceptable risk to the aquatic environment. There is no need for further testing or risk reduction measures based on the notified use pattern and import volumes.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

The notified polymer will be imported in ready to use form, and therefore no worker exposure is expected prior to end use in hair salons. Salon workers may have regular dermal contact with the dyes and conditioners containing the notified polymer; however the use of gloves (supplied in the dye kit) is recommended for workers applying hair dyes on a regular basis.

9.2.2. Public health – exposure assessment

There will be regular dermal exposure (hands and scalp) and possible ocular exposure during application of the dye and conditioner. While the supplied gloves may be worn, particularly during application of the dye, exposure via the scalp is unavoidable. The maximum concentration of notified polymer will be 3.75 % in the conditioner.

9.2.3. Human health - effects assessment

No toxicology data was submitted for the notified polymer. The notified polymer is a surfactant, and may be expected to have some irritant properties at high concentrations. The high molecular weight of the notified polymer should preclude absorption across biological membranes, and systemic toxicity is not expected.
As no data has been submitted the notified polymer cannot be classified under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

9.2.4. Occupational health and safety – risk characterisation

Salon workers may have repeated dermal exposure to the notified polymer, but it is likely that gloves will be worn during application of the dye preparation due to the presence of potentially hazardous or staining ingredients. Based on the low expected hazard and the use of protective measures, it is not likely that the notified polymer will result in significant occupational health and safety risk.

9.2.5. Public health – risk characterisation

The notified polymer is present in hair dye and conditioner products at a concentration of up to 3.75 %. At this concentration it is not expected to cause irritation of the skin or eyes. The notified polymer has a high molecular weight and is unlikely to penetrate biological membranes. At the concentration of notified polymer in the imported products, the low expected systemic toxicity of the polymer suggests that it will not pose a significant hazard to public health when used in the proposed manner.

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

On the basis of the PEC/PNEC ratio the notified polymer is deemed to pose an acceptable risk to the aquatic environment.

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 Negligible Concern to public health when used as a component of hair dye kits as described in the notification.

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 product containing 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 ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during salon application:
  - 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.

Disposal

- The notified polymer should be disposed of either by incineration, into landfill or recycled.

Emergency procedures

- Spills/release of the notified polymer should be contained as described in the MSDS (contained by absorbant material such as vermiculite or sand) prior to disposal.

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 Section 64(1) of the Act; if

- the import volume is increased above currently assessed level of three tonnes per annum, in which case a secondary notification containing a full suite of aquatic toxicity data should be submitted; additional environmental fate data, particularly with respect to adsorption characteristics of the notified polymer would also be helpful;

or

(2) Under Section 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.

13. BIBLIOGRAPHY

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