File No PLC/821

February 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)

FULL PUBLIC REPORT

1-Dodecanaminium, N,N-dimethyl-N-[3-[(2-methyl-1-oxo-2-propenyl)amino]propyl]-, chloride, polymer with N-[3-(dimethylamino)propyl]-2-methyl-2-propenamide, 1-ethenylhexahydro-2H-azepin-2-one and 1-ethenyl-2-pyrrolidinone (9CI) (INCI: Polyquaternium-69)

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

TABLE OF CONTENTS

FULL PUBLIC REPORT

1-Dodecanaminium, N,N-dimethyl-N-[3-[(2-methyl-1-oxo-2-propenyl)amino]propyl]-, chloride, polymer with N-[3-(dimethylamino)propyl]-2-methyl-2-propenamide, 1-ethenylhexahydro-2H-azepin-2-one and 1-ethenyl-2-pyrrolidinone (9CI) (INCI: Polyquaternium-69)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
ISP (Australasia) Pty Ltd (ABN 27 000 011 923)
73-75 Derby Street Silverwater NSW 2128

NOTIFICATION CATEGORY
Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Other names, Molecular formulae, Molecular weight, Polymer constituents, Residual monomers/impurities, Import volume and Site of reformulation.

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 (2008)

2. IDENTITY OF CHEMICAL

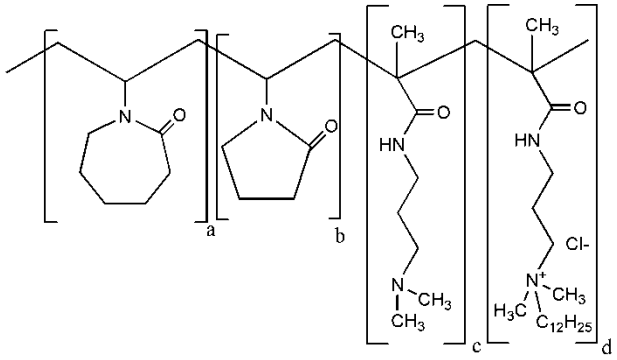
CHEMICAL NAME
1-Dodecanaminium, N,N-dimethyl-N-[3-[(2-methyl-1-oxo-2-propenyl)amino]propyl]-, chloride, polymer with N-[3-(dimethylamino)propyl]-2-methyl-2-propenamide, 1-ethenylhexahydro-2H-azepin-2-one and 1-ethenyl-2-pyrrolidinone (9CI)

MARKETING NAME(S)
Component of AquaStyle 100
Component of AquaStyle 300

OTHER NAME(S)
Polyquaternium-69 (INCI)
Polymeric quaternary ammonium salt composed of vinyl caprolactam, vinylpyrrolidone, dimethylaminopropyl methacrylamide (DMAPA) and methacryloylaminopropyl lauryldimonium chloride (MAPLDAC)

CAS NUMBER
748809-45-2

STRUCTURAL FORMULA



MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >10,000 Da

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains cationic (ammonium) and potentially cationic (amine) groups that are of high environmental concern. However, given the FGEW > 5000 Da the notified polymer meets the low charge density criteria for polymers of low concern.

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:	White fluffy powder
Melting Point/Glass Transition Temp	Decomposed without melting between 170 and 400°C
Density	1229.3 kg/m^3 at 20°C
Water Solubility	107.1 g/L at 20°C The solubility was determined by the shake flask method with nonspecific analysis (DOC). Gel permeation chromatography revealed that more than 90% of the dissolved material had relatively low molecular weight, but a number of higher molecular weight components were also present. The pH of the solution was 4.9.
Dissociation Constant	The notified polymer contains quaternary ammonium functionality, which will remain ionised throughout the environmental pH range of 4–9, and tertiary amine functionality with the potential to become cationic under the same conditions.
Particle Size	Mass Median Aerodynamic Diameter (MMAD) = 9.1 μm Proportion below 100 μm = 99.99 % Proportion below 10 μm = 63.04 %
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	1	1	1	1	1

Use
A hair fixative (at concentrations of 0.25-4%) in hair styling products including clear and cream gels, aerosol and nonaerosol mousses, styling lotions, spritzes and sprays. These products are intended to be used by professional hairdressers (~ 2% import volume) and public consumers (~ 98% import volume).

Mode of Introduction
The notified polymer will not be manufactured in Australia but will be imported into Sydney harbour as a yellow viscous liquid containing up to 40% notified polymer in ethanol and water. The imported material will be contained in 400 lb (181 kg) tight head polyethylene drums or 44 lb (20 kg) tight head polyethylene jerry cans and directly transported by road from the dockside to the customer. Customers will reformulate the imported material into packaged finished 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. Results of tests conducted on aqueous solutions containing 40% notified polymer are summarised below.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
1. Rat, acute oral	LD50 > 2000 mg/kg bw	yes	OECD TG 425
2. Rabbit, acute dermal	LD50 > 2000 mg/kg bw	yes	OECD TG 402
3. Rabbit, skin irritation	non irritating	no	OECD TG 404
4. Rabbit, eye irritation	non irritating	yes	OECD TG 405
5. Genotoxicity - bacterial reverse mutation*	non mutagenic	yes	OECD TG 471
6. Genotoxicity - in vitro chromosomal aberration*	non genotoxic	no	OECD TG 473
7. Human, skin irritation and contact sensitisation	non irritating, no evidence of sensitisation	yes	Repeated Insult Patch Test
8. Human, photoallergy	non photoallergenic	no	Photoallergy (Protocol No.: 7.05, Consumer Product Testing Co.)
9. Human, phototoxicity	non phototoxic	no	Phototoxicity (Protocol No.: 7.04, Consumer Product Testing Co.)

*** Test conducted on 100% notified polymer**

Acute oral toxicity
There were no abnormal physical signs in 4/5 rats tested, but one animal showed signs of few faeces, lethargy, emaciation, erect fur (piloerection), red pigment-stained tears (chromodacryorrhea), tremors, sagging eyelids, wet and soiled anogenital area and weight loss during the first week of the study. Lung abnormalities observed in this animal at the time of necropsy indicated that aspiration due to a dosing error had occurred. In the second week of the study, the same animal increased in body weight and appeared completely normal by day 14, except for anogenital hair loss (alopecia). The notified polymer solution is not considered acutely toxic based on this study.

Acute dermal toxicity
At 2000 mg/kg of body weight, 2/10 animals exhibited very slight oedema at 24 hours, and by day 7 all ten animals showed dermal responses, ranging from very slight to moderate oedema and very slight to moderate-severe erythema. At day 14, 6/10 animals showed reduced symptoms (very slight or slight erythema and very slight or slight oedema). There was no mortality or signs of systemic toxicity and all animals gained normal body weight. The notified polymer solution is not considered to cause dermal toxicity based on the results of this study.

Eye irritation

Three rabbits showed slight redness and slight swelling of the conjunctiva in the treated eye at the 24-hour observation. One of three animals also exhibited slight conjunctival discharge. All signs of irritation cleared by 48 hours. The notified polymer solution is not considered irritating to the eye.

Genotoxicity – bacterial
There was a small but statistically significant increase in revertant colonies in *S. typhimurium* strain TA1535 in the absence of metabolic activation at 1000 μg/plate in Experiment 1 and at 800 μg/plate in Experiment 2, but these results were not observed at the higher doses tested. The study authors concluded that these increases were due to chance occurrences and were not an indication of mutagenic effects. The notified polymer is not considered to be mutagenic based on this study.

Human skin irritation and contact sensitisation
In a human Repeated Insult Patch Test, 106 subjects were exposed to 0.2 g of the notified polymer solution (40%) 3 times per week over 3 weeks, followed by a challenge patch approximately 2 weeks after the induction applications. There were no skin reactions (score 0) in 104/106 subjects throughout the study period. Subject # 30 and #41 exhibited 'barely perceptible' or spotty erythema after the challenge application at the 24 hour and 72 hour observation, respectively. Subject #30 also displayed papules at this site, which had cleared by 72 hours. The investigators stated that the responses were weak and transitory and not considered clinically significant. Under the conditions of this study, the notified polymer is not considered to have the potential for dermal irritation or allergic contact sensitisation.

All results indicate that the notified polymer is of low hazard.

Occupational Health and Safety Risk Assessment
Dermal and ocular exposure to up to 40% of the notified polymer may occur due to splashes and spills during manual weighing, sampling, cleaning, maintenance and packaging. Exposure is expected to be limited by the use of PPE such as safety glasses and gloves. Engineering controls (e.g. extraction hoods or vacuum tubes) may minimise inhalation of vapours or aerosols generated during the mixing process and reduce the potential for ethanol vapour exposure (present as solvent).

Intermittent and wide-dispersive use is expected to occur among hairdressers and salon workers who are likely to come into skin contact when handling finished hair styling products containing up to 4% of the notified polymer.

Although exposure to the notified polymer could occur, the risk to workers is considered to be low due to the low expected exposure levels and low hazard of the notified polymer at the concentration introduced.

Public Health Risk Assessment
Since the notified polymer will be in products sold to the general public, widespread public exposure is expected. Exposure to the notified chemical will vary depending on individual use patterns. Using the *SCCP's Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation (2006)*, the calculated daily exposure level is 1.0 g/day. Using a default body of weight of 60 kg and the concentration of the notified polymer as 4%, the systemic exposure dosage is calculated to be 0.67 mg/kg bw/day.

Although the public will be exposed to the notified polymer during use of hair styling products containing up to 4% of the notified polymer, the risk to public health is considered to be low due to the predicted low hazard of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation
The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified or analogue polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Fish Toxicity	EC50 = 127 mg/L	no	OECD TG 203
Daphnia Toxicity	EC50 > 134 mg/L	yes	OECD TG 202

Algal Toxicity	EC50 = 6.1 mg/L	yes	OECD TG 201
Inhibition of Bacterial Respiration	EC50 > 1500 mg/L	no	OECD TG 209

The results for fish, daphnids and bacteria were indicative of low hazard. The notified polymer was toxic to algae. The predicted no effect concentration can be estimated as 61 μg/L.

Environmental Risk Assessment
Based on the hypothetical worst case assumption that all of the notified polymer will be discharged to water, and standard assumptions regarding water use by the Australian population, the PECs of the notified chemical in fresh and marine water may approximately be 0.64 μg/L and 0.064 μg/L, respectively. As the PEC/PNEC ratio is in the order of 0.01 for freshwater and 0.001 for the ocean, the notified polymer is not considered to pose a risk to the 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 PEC/PNEC ratio and 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 by landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by containment, 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;
- the notified polymer is introduced in a solid/powder form;
- the concentration of the notified polymer being introduced has increased from 40%;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from an ingredient in hair styling products, or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- 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.

Material Safety Data Sheet
The MSDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.