File No SAPLC/83

17 March 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in MiruStyle X-HP

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 Water Resources has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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

Polymer in MiruStyle X-HP

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Croda Singapore Pty Ltd Trading as Croda Australia (ABN 34 088 345 457)
Ground Floor, Suite A1,
44-46 Mandarin Street,
VILLAWOOD, NSW 2163

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, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, and Import Volume.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Previously submitted Form 15 - Advice of introduction of a new chemical for cosmetic use.

NOTIFICATION IN OTHER COUNTRIES
Not known.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in MiruStyle X-HP
INCI name: Sodium Laneth-40 Maleate/Styrene Sulfonate Copolymer

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

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

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	Light yellow liquid.
Melting Point/Glass Transition Temp	The notified polymer is liquid at room temperature and is never isolated from solution.
Density	The notified polymer is never isolated from solution.
Water Solubility	The notified polymer is soluble in water and never isolated from solution.
Dissociation Constant	A dissociation constant has not been established for the notified polymer as it has a distribution of molecular species with multiple repeating moieties. The polymer contains carboxylic acid and alcohol groups. The pKa for the carboxylic acid groups are greater than 5 and the dissociation of the alcohol groups are not expected under normal environmental conditions.
Reactivity	Stable under normal conditions of use.
Degradation Products	None under normal conditions of use. The notified polymer contains linkages that may hydrolyse under extreme pH. However, significant hydrolysis is unlikely in the environmental pH range of 4-9.

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	1-3	1-3	1-3	1-3

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will be imported into Australia either as a component of a finished hair product (2-10%) or as a raw material for reformulation into hair products (15% in water). The notified polymer will be imported in 25 kg plastic pails when imported as a raw material. The notified polymer and products containing the notified polymer will be transported by road or rail for distribution.

Reformulation processes

Products containing the notified polymer which are imported as finished products will not be reformulated or repackaged in Australia. Such products will be stored at the notifier's warehouse before distribution to customers.

The notified polymer will be reformulated into a finished cosmetic product only when imported as a raw material. The notified polymer will be transported by road or rail in plastic pails to the site of formulation where it will be stored and formulated into hair care products.

During the manufacture of hair care products, workers will weigh and dispense the required amount of the notified polymer into a mixing vessel. Other components of the formulation are added and the mixture is blended under enclosed and automated settings. Sampling and quality control testing of the formulated product is conducted prior to packaging. The finished formulation is then transferred via pipes and pumps to a storage tank, equipped with a filler machine, and mechanically poured into the product containers. The product containers are then sealed and packaged for distribution to customer sites.

Use

The notified polymer is a hair styling polymer that is designed to protect hair from heat damage. The notified polymer is used as a component of cosmetic hair styling products and shampoos (2-10%) and may be used daily by hairdressers or the general public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

During the reformulation of the notified polymer (imported at 15% in water) into finished hair products, personnel will wear eye protection and appropriate protective clothing. The notified polymer will be present at relatively low concentrations (2-10%) in the finished hair products. Therefore, the notified polymer would not be considered an occupational health risk after formulation, even if some exposure should occur.

When used in hairdressing salons, the notified polymer will be present at approximately 2-10% of the finished shampoo or styling formulation (gel, spritze, serum or mousse). It will be applied to the hair and may be rinsed out after use (as is the case with shampoos). Hairdressers are expected to follow good hygiene practices after application of the product.

PUBLIC EXPOSURE

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.

Small quantities of the finished product (approximately 8 g for shampoo and 5 g for hair styling products) are applied to hair. It is predicted that 1% of the applied shampoo and 10% of the applied hair styling product will be retained on the skin. Thus, a maximum of 0.008 g/day of the notified polymer will remain on the skin after use with shampoo (based on one application per day) and 0.1 g/day after use with hair styling products (based on two applications per day) (SCCNFP/0321/02).

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 Method*
1. Skin irritation, human patch test	no potential for dermal irritation or allergic contact sensitisation	no	no	repeated insult patch test
2. Irritation, HET-CAM test	practically non-irritating	no	yes	modified HET-CAM test
3. EpiDerm Skin Model	non-irritating	no	yes	MatTek Corporation
4. Genotoxicity – bacterial reverse mutation	non-mutagenic	no	no	OECD TG 471

All results were indicative of low hazard.

The notified polymer has a high number average molecular weight (NAMW >30,000) thus it is not expected to cross biological membranes nor penetrate the skin. Test studies indicate that the notified polymer does not indicate a potential for dermal irritation or allergic contact sensitisation when 0.2 mL of the product MiruStyle X-HP (20% dilution) was applied via patches to human skin.

An *in vitro* study (Hen's Egg Test – Utilising the chorioallantoic membrane – HET/CAM) indicates that MiruStyle X-HP would have practically no irritation potential *in vivo* at 5%, 10% and 20% (Draize test equivalents). Some irritant effects were observed in the CAM including, hyperaemia, minimal haemorrhage ("feathering'), haemorrhage (obvious leaking), and coagulation and/or thrombosis.

The Ames test conducted found the product MiruStyle X-HP to be negative and not mutagenic under the conditions of the test.

The product MiruStyle X-HP, tested at 100%, was showed to have an expected *in vivo* dermal irritancy potential in the non-irritating range under the conditions of the MatTek Corporation EpiDerm *in vitro* toxicity testing system. Some inhibition of the reduction of tetrazolium salt by mitochondrial enzymes was observed (16% at 1 hour, 15% at 4.5 hours, and 22% at 20 hours).

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Although exposure to the notified polymer could occur during formulation, 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 hair styling products and shampoos containing 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

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release of the notified polymer or finished product may occur in the rare event from accidental spillage during transport when packaging is damaged, or loss during manufacture and disposal.

During formulation a small amount of the notified polymer could be washed from machinery during cleaning. This is normally treated as site industrial waste and dealt with by licensed disposal contractors. Some will ultimately be released into the sewer. Empty import containers with any remaining residual material will be disposed of to landfill.

The finished product will be applied to hair. Therefore, the majority of the notified polymer is expected to be washed off and enter the sewer, with the remainder disposed to landfill as residues in product containers.

Sludge containing the notified polymer will be disposed of to landfill.

ENVIRONMENTAL FATE

The notified polymer is water soluble and expected to be hydrolytically stable. On the basis of water solubility, the notified polymer is likely to be mobile in soils, and should work its way into the grass root zone and below. The notified polymer should not hydrolyse but is expected to slowly degrade into oxides of carbon and water. Incineration of the notified polymer will result in the generation of water vapour and carbon dioxide. The notified polymer's high molecular weight will preclude absorption across biological membranes and thus it is unlikely to bioaccumulate.

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 nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. Whether this applies to the notified polymer is unclear. 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 sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated to be 1.84 g/L.

Total annual volume	3,000 kg
Proportion released to sewer	95 %
Annual quanity of chemical released to sewer	2850 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365 days

Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, the PECs of the notified polymer in freshwater and marine water may approximate 1.84 and 0.18 g/L, respectively.

While no PNEC can be derived the expected aquatic toxicity is likely to be > 1 mg/L. Consequently, release of the polymer to the water compartment at the relatively low levels estimated above, is unlikely to present an unacceptable environmental risk.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

8.2. Level of Concern for Public Health

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

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.

- Manufacturing personnel should wear eye protection and appropriate protective clothing when formulating hair styling products containing the notified polymer.

- 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 to landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled by containment and disposal to landfill.

11. 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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of cosmetic hair styling products and shampoos (2-10%), or is likely to change significantly;
- the amount of chemical being introduced has increased from 3 tonnes, or is likely to increase, significantly;
- if the chemical 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.