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

FULL PUBLIC REPORT

Polymer in Fixate® G-100

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**Director
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FULL PUBLIC REPORT**Polymer in Fixate® G-100****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Croda Singapore Pty Ltd (ABN 34 088 345 457) of 44-46 Mandarin Street, Villawood NSW 2163.

NOTIFICATION CATEGORY

Synthetic 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, Hazardous and Non-hazardous Impurities/Residual Monomers, Additives/Adjuvants, Import Volume, and Site of Manufacture/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

USA TSCA FDA Exemption (2001)

Canada NSN (2002)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Fixate® G-100

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Not applicable
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazardous Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria. FGEW requirements do not apply due to high molecular weight, but the notified polymer does not contain reaction functional groups with FGEW <5000.

4. INTRODUCTION AND USE INFORMATION

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	3-10	3-10	10-30	10-30

USE

As a hair fixative polymer (<5%) for use in non-aerosol styling products such as gels, spray gels, mousses, creams, waxes, and other non-aerosol systems.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will not be manufactured in Australia but will be imported as a component of the product Fixate® G-100 (27% total solids in water) in 204 kg net steel drums. The total solids vary as adjustments are made to ensure that the product is in the correct pH range. Fixate® G-100 will be transported directly from the dockyards to the warehouse of a manufacturer of hair fixative products which will be sold to consumers through the retail sector.

At the manufacturer's warehouse, Fixate® G-100 drums will be stored on racks in banded areas. Following quality control analysis by laboratory technicians, the drums will be transferred via fork-lifts to the formulation areas. The notified polymer will be manually added to a stainless steel blender (1000 L capacity) with other ingredients and mechanically mixed under local exhaust ventilation. The resulting mixture will be pumped into a sealed tank, which will then be transferred by a pallet truck to the packaging floor for pumping via pipes into a range of plastic retail containers, typically 100-250 mL. The end-user products containing <5% notified polymer will then be transported to retail outlets.

Consumers will style their hair with various fixative products for few minutes a day and it is expected that these will be left on for up to 12 hours. The product is expected to be washed off at the end of each day and end up in the sewer system.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure and Fate

Since local manufacture of the notified polymer will not take place in Australia, there will be no environmental exposure associated with this process. Environmental releases during the blending process are minimised by the use of sealed systems and the total losses due to equipment cleaning and spills etc are estimated to be up to 600 kg. Accidental spillages (less than 100 kg) will be collected with absorbent material and disposed of to landfill in accordance with Local, State and Federal regulations.

It is estimated up to 150 kg of residues may be left in empty import drums, which will be disposed of to landfill. The liquid waste stored in drum tanks will be collected by licensed waste contractors and disposed of to authorised liquid waste treatment facilities in accordance with Local, State and Federal regulations.

The majority of the notified polymer imported will be released into the sewerage systems throughout Australia through washing of hair. The consumer containers in which the formulated product will be sold and the residues they contain will be disposed of in domestic landfill.

Although linkages are present in the notified polymer that could be expected to undergo hydrolysis under extreme conditions, significant hydrolysis is unlikely in the environmental pH range of 4 to 9. The notified polymer is expected to be soluble in water under the basic conditions generally found in the sewer (pH 8) and be mobile in both the aquatic and terrestrial compartments. However, eventual association with soil and sediment is expected where the notified polymer will slowly degrade through biological and abiotic processes to water and oxides of carbon and nitrogen. Residual polymer disposed of to landfill is also expected to slowly adsorb to soil/sediment particles and slowly destroyed by similar mechanisms to those operating in sediments.

6.2. Summary of Occupational Exposure

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Dermal and ocular exposure can occur during certain formulation processes. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

6.3. Summary of Public Exposure

Wide-dispersive use with intermittent dermal contact and possibly accidental ocular contact with hair fixative products containing the notified polymer is expected to occur among public consumers. For purposes of estimating exposure, calculations are based on use information of non rinse-off hair styling products (eg 5 g/application and 2 applications per day) as outlined in the Annex 5 of the *Notes of Guidance for Testing of Cosmetic Ingredients for their Safety Evaluation (SCCNFP, 2000)*, and assumptions that these hair fixative products are used extensively and the polymer concentrations in these products are used at the maximum levels. The total daily exposure of an individual to the notified polymer is estimated to be $5 \text{ g} \times 2 \times 5\% = 0.5 \text{ g}$. The high molecular weight of the notified polymer would preclude skin absorption, and thus systemic exposure would not be a concern.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White, low viscosity, aqueous dispersion with butterscotch odour
Melting Point/Glass Transition Temp	Not determined. The notified polymer is offered only in an aqueous dispersion.
Density	1000 kg/m ³ (water)
Water Solubility	Dispersible in water
Dissociation Constant	The aqueous dispersion of the notified polymer contains carboxylate groups as amine salts (pH 5.8-6.3)
Reactivity	Stable under normal environmental conditions
Degradation Products	CO, CO ₂ , acrylate monomers, and hydrocarbons

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological studies were submitted:

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Rat, acute dermal (limit test)	LD50 >2000 mg/kg bw	no	no
Rabbit, skin irritation	Slightly irritating	no	yes
Rabbit, eye irritation	Slightly to moderately irritating	no	yes
Human, skin sensitisation	no evidence of sensitisation	no	no

8.1.1 Discussion of observed effects

All results were indicative of low hazard.

Slight erythema observed at the intact skin sites of three rabbits exposed to an analogue polymer, the notified polymer in free acid form, (4 hours, semi-occluded) appeared normal at the 48-72 hour observations. The primary irritation index was calculated to be 0.6 (slightly irritating). However, no effect was observed when tested with the 12% dispersion of the notified polymer, which is neutralised with an amine.

In the eye irritation tests, minimal to moderate conjunctival irritation was observed in all treated eyes one hour after treatment. Minimal conjunctival irritation was noted in all eyes treated with the 12%

notified polymer dispersion at the 24 and 48-hour observations. Three rabbits eyes treated with 12% Fixate® G-100 (3% notified polymer) appeared normal after 24 hours while minimal conjunctival irritation persisted in all eyes treated with 100% Fixate® G-100 (27% notified polymer), with two treated eyes appeared normal at the 48-hour observation. By 72 hours post treatment, all eyes were normal. No corneal or iridial effects were noted with all tested polymer concentrations.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The available test results support the conclusion of low hazard.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted. A ready biodegradability test report for an analogous polymer was provided.

<i>Endpoint</i>	<i>Result and Conclusion</i>
Ready Biodegradability	Not readily biodegradable

9.1.1 Discussion of observed effects

An analogous polymer used in a ready biodegradability test (OECD TG 301B – CO₂ Evolution Method) attained 79% degradation after 28 days, exhibiting its potential for rapid biodegradation. However, as it failed to satisfy the OECD 10-day window validation criterion requiring $\geq 60\%$ degradation within 10 days after reaching 10% degradation, the test substance was not considered to be readily biodegradable.

9.2. Environmental Hazard Assessment

Due to the lack of aquatic toxicity data a predicted no effect concentration (PNEC) could not be derived for the aquatic ecosystems.

According to Nabholz et al. (1993) polyanionic polymers that are polycarboxylic acids with molecular weights >1000 and water-soluble are known to be toxic only to green algae. The 96-hour EC₅₀ values ranging from 1 to 100 mg/L (moderate toxicity) are quoted and the mode of toxic action on algae is overchelation of nutrient elements thus resulting in growth inhibition. Highest toxicity occurs when there is a carboxylic acid on every other (or alternating) carbon(s) in the polymer backbone for which there is a high potential for the notified polymer. However, when calcium (as calcium carbonate in water) is added to the polymer (satisfying the anionic charges) the toxicity to algae has shown to be considerably mitigated.

10. RISK ASSESSMENT

10.1. Environment

All of the imported notified polymer will eventually be released into the environment with the majority expected to be discharged into sewerage systems after use. Release of up to 850 kg per annum may occur during the blending operations with up to 250 kg disposed of to landfill (as spills and import drum residues) and the remainder treated in an authorised liquid waste treatment facility. The residue in consumer containers will also be disposed of in landfill.

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

Assuming that the majority of the imported polymer is eventually released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 82 kg/day using a maximum import of 30 tonnes per annum. Based on a national population of 20 million and that each person contributes an average 200 L/day to overall sewage flows, the PEC in sewage effluent on a nationwide basis is estimated as 20.5 µg/L. Based on dilution factors of 1 and 10 for inland and ocean discharges of treated effluents, the PECs of the notified polymer in freshwater and marine water may approximate

20.5 µg/L or 2.05 µg/L, respectively.

Based on Nabholz et al. (1993), while the safety margin appears relatively narrow by assuming the maximum laboratory toxicity of 1 mg/L and a worst case freshwater concentration of 20.5 µg/L, this will be increased by chelation to calcium and other ions. The actual PECs can be also expected to be lower, given that the concentration of the notified polymer will further reduce due to:

- removal via treatment and/or degradation in the liquid waste and sewerage treatment facilities; and
- adsorption to sediment and further degradation in the aquatic environment.

Based on the proposed use pattern, the release of the notified polymer to the environment is expected to be diffused and 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. Also, based on the biodegradability test results of an analogous polymer, the notified polymer is expected to degrade eventually with abiotic or slow biotic processes expected to be largely responsible for this.

10.2. Occupational Health and Safety

The OHS risk presented by the notified polymer is expected to be low. 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.

10.3. Public Health

Members of the public may make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is present at low concentrations and unlikely to be bioavailable.

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

11.1. Environmental Risk Assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

11.2. Human Health Risk Assessment

11.2.1. Occupational health and safety

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

11.2.2 Public health

There is Low Concern to public health when used in the proposed manner.

12. MATERIAL SAFETY DATA SHEET

12.1 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.

13. 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 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 in accordance with Local, State and Federal regulations. This will include disposing of spillages and container residues into landfill and the liquid waste collected by licensed waste contractors into authorised liquid waste treatment plants.
- The MSDS advises waste product when it is in liquid form (as supplied) should be incinerated at an approved incineration facility in accordance with government regulations.

Emergency procedures

- Spills/release of the notified polymer should be handled as outlined in the MSDS and in accordance with government regulations, ie contain spill and do not flush liquid into public sewer, water systems or surface waters.

13.1. 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.

14. BIBLIOGRAPHY

Nabholz JV, Miller P & Zeeman M (1993) Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five. In: Landis WG, Hughes JS & Lewis MA ed. Environmental Toxicology and Risk Assessment, ASTM STP 1179. Philadelphia, American Society for Testing and Materials.

SCCNFP (2000) Notes of guidance for testing of cosmetic ingredients for their safety evaluation [SCCNFP/0321/00 Final]. The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers.