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

FULL PUBLIC REPORT

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer

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 and Heritage.

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**Director
Chemicals Notification and Assessment**

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FULL PUBLIC REPORT**Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Orica Limited (ABN 24 004 145 868) of 1 Nicholson Street Melbourne VIC 3000

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, Polymer Constituents, Use Details, 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

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer
Simulgel NS (<60% notified polymer)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >10000

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	N/A
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

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>	0-1	1-3	1-3	1-3	1-3

USE

A thickener (at <3%) for cosmetic gels, creams and lotions, which is compatible with acid, alkaline and oxidising media.

5. PROCESS AND RELEASE INFORMATION

5.1. Operation Description

The notified polymer will not be manufactured in Australia but will be imported from Europe as a <60% compound mixture (Simulgel NS) for use in formulating skin and hair care preparations.

At a customer formulation plant, a storeperson will deliver palletised packages of Simulgel NS by forklift to various work areas as required, for example, warehouse or batch formulating area. Professional compounders will weigh and manually add required quantities of Simulgel NS and other ingredients into a mixing tank under local exhaust ventilation. Following quality control analyses by a chemist, the resulting mixture will be transferred to packing lines for filling into retail bottles, usually sealed with screwcaps. These mixing and dispensing processes will be automated and occur in an enclosed system or in one designed not to create aerosols and dust hazards. The finished cosmetic products containing the notified polymer at <3% will then be stored and delivered to retailers for distribution to consumers.

Consumers (estimated to be around 300,000) will take care of their hair and skin by applying cosmetic gels, creams and lotions one to two times a day. It is expected that these preparations will be rinsed-off or left on, and then be washed off at the next washing and end up in the sewer system.

6. EXPOSURE INFORMATION

6.1. Summary of Environmental Exposure

Import and transportation

Environmental release of the notified polymer is unlikely during importation, storage and transportation although spillages during a transport accident could be the most likely reason for environmental release. The notified polymer will be stored in drums packaged onto pallets.

Reformulation

Environmental release of the notified polymer during reformulation is expected to be low as formulation and dispensing will be conducted in a closed system. The reformulating process is a batch process with a batch typically being 6 tonnes and containing approximately 180 kg of notified polymer.

The reformulation equipment will be cleaned with water. It is estimated that 2-3% of the final product are rinsed into the waste water, which will then go to a biological treatment plant.

Use

End products containing the notified polymer will be widely distributed and used throughout Australia. Types of containers will include 30-50 and 150 mL HDPE plastic and glass bottles. Approximately <1% of the notified polymer will remain in emptied containers, which will be discarded to landfill or recycled through plastic bottle recycling programs.

The notified polymer (up to 3000 kg/year) will be used in a range of cosmetic products that will mostly be washed off to the sewer.

The notified polymer is not readily soluble but dispersible in water. Due to its high molecular weight,

when released to the sewer and landfill, the notified polymer is expected to have a high affinity with the sludge, soil and sediment. The notified polymer is likely to slowly degrade through abiotic and biotic processes to water and oxides of carbon, sulfur and nitrogen. Incineration of the notified polymer will produce water and oxides of carbon, sulfur and nitrogen.

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

Cosmetic products containing the notified polymer are for sale to the general public. Wide dispersive use with dermal contact and possibly accidental ocular contact with the notified polymer is therefore expected to occur among public consumers. However, exposure will be low because the notified polymer is present at low concentrations and applied in small quantities.

7. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	White viscous liquid with characteristic odour
Melting Point/Glass Transition Temp	6°C
Density	1100 kg/m ³ at 25°C
Water Solubility	Dispersible in water
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

8. HUMAN HEALTH IMPLICATIONS

8.1. Toxicology

The following toxicological endpoints were submitted:

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>
Acute oral – rat (full report not provided)	LD50 >2000 mg/kg bw	no	no
Skin irritation – human	non-irritating	no	no
Eye irritation – in vitro	non-irritating	no	no
Skin sensitisation – human	no evidence of sensitisation	no	no
Genotoxicity – bacterial reverse mutation	non mutagenic	no	no

All results were indicative of low hazard.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The results of toxicity testing submitted support this conclusion.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

No toxicological data were submitted.

9.2. Environmental Hazard Assessment

The nature of the notified polymer (containing anionic charges) indicates that the polymer is expected to adsorb onto particles of sediment and sludge, leaving a small amount in the water compartment. Hence, the environmental exposure and environmental hazard overall is expected to be low.

10. RISK ASSESSMENT

10.1. Environment

Most of the polymer will be washed into the sewer. If a worst case scenario is considered as follows with no removal of the notified polymer from the sewage treatment plant (STP), the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated to be 2 µg/L.

Amount entering sewer annually	3000 kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365

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 2.0 or 0.2 µg/L, respectively. As the polymer is expected to be associated with sludge, the level in the environment will be significantly lower than indicated. No ecotoxicological data was provided for the notified polymer, but due to the low environmental concentration the risk to the environment is expected to be low.

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

Given the notified polymer will only be used at low concentrations (<3%) in cosmetic formulation and its high molecular weight will preclude systemic absorption, the risk to public health is determined to be low.

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 No Significant Concern to public health when used as directed.

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.

- In the interest of occupational health and safety, the following guidelines and precautions should be observed for use of Simulgel NS and its end use products:
 - Enclosed and automated processes at the reformulation and packaging sites, including enclosed and automatic transfer lines/pumps for loading and emptying of the mixing and transport vessels;
 - Adequate ventilation for the plant operators, including use of local exhaust ventilation on weighing and addition to the blending vessel and on QC testing.
 - Adequate training for staff in safe handling procedures;
 - Implementation of general health surveillance and monitoring programs as required.
- 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 reformulation plant to minimise environmental exposure during formulation and packaging of the skin and hair care products containing the notified polymer:
 - Regular maintenance of bunding, drains, intercept pits and effluent treatment plants.

Disposal

- The notified polymer wastes should be disposed of by incineration or in landfill in accordance with State/Territory waste management regulations.
- The imported product mixture containing the notified polymer should not be disposed of to sewer.

Emergency procedures

- Spills/release of the notified polymer should be handled by containing and adsorbing with non-combustible materials, either sand or diatomaceous earth, vermiculite or saw dust, then placed in a sealable container for disposal to landfill or in accordance with local authorities. Do not allow entry to stormwater drains or waterways.

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.

No additional secondary notification conditions are stipulated.