

File No PLC/804

March 2009

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

FULL PUBLIC REPORT

Castor Isostearate Succinate

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**

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FULL PUBLIC REPORT**Castor Isostearate Succinate****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Cee Chem Australia Pty Ltd (ABN 61 081 398 192)
227A Belmore Road
Riverwood, NSW 2210

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

No details are claimed exempt from publication.

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

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Zenigloss
Zenigloss UP
Zenigloss UPH (90% notified polymer with 10% hydrogenated castor oil)
Zenigloss S (90% notified polymer with 10% beeswax)

CHEMICAL NAME

Castor oil, polymer with succinic acid, isostearates

CAS NUMBER

321573-76-6

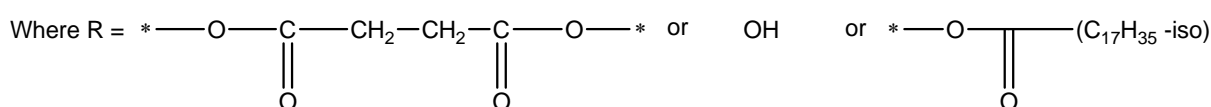
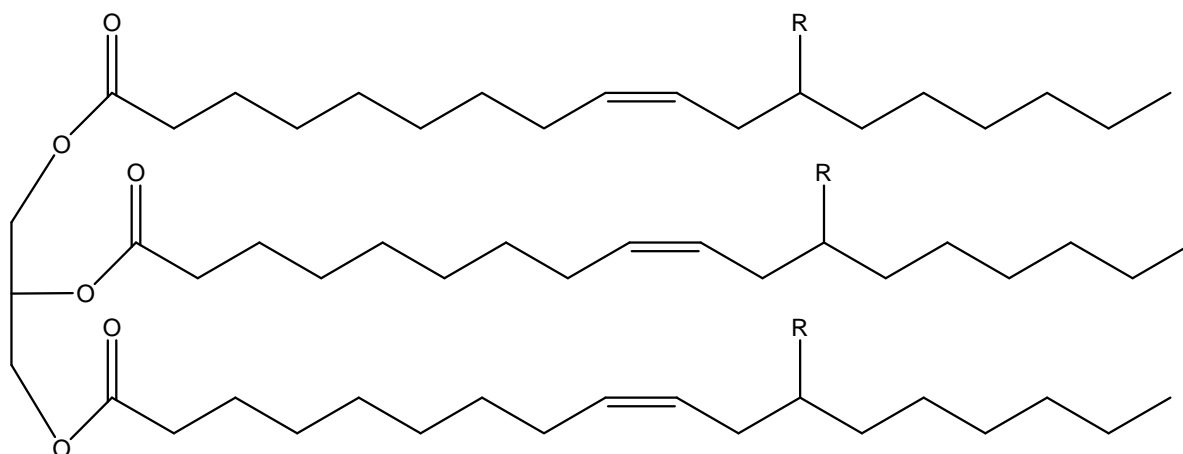
OTHER NAME(S)

INCI name: Castor Isostearate Succinate

MOLECULAR FORMULA

Unspecified

STRUCTURAL FORMULA



Typical structure with only the main triglyceride (i.e. ricinoleic acid derivatives) depicted.

Castor oil is a triglyceride containing the following fatty acids:

Ricinoleic acid (141-22-0) 87-91%
 Stearic acid (57-11-4) and palmitic acid (57-10-3) 2%
 Oleic acid (112-80-1) 4-5%
 Linoleic acid (60-33-3) 4-5%
 Dihydroxystearic acid (26248-43-1, 120-87-6) 1%

The castor oil is covalently bonded to the other monomers in the notified polymer to form a polyester. The polyester is formed by a condensation reaction between the carboxylic acid functional groups on the isooctadecanoic and butanedioic acids and the secondary alcohols on the dihydroxystearic and ricinoleic acids.

The approximate concentrations of the fatty acids were sourced from Ullmann's Encyclopedia of Industrial Chemistry (7th Ed, 2007).

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	3814 Da
Weight Average Molecular Weight (Mw)	8457 Da
Polydispersity Index (Mw/Mn)	2.2
% of Low MW Species < 1000 Da	1%
% of Low MW Species < 500 Da	0%

POLYMER CONSTITUENTS

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
Isooctadecanoic acid	30399-84-9	3	0
Butanedioic acid	110-15-6	8.5	0
Castor oil	8001-79-4	88.5	0

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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:	Transparent amber viscous liquid
Melting Point/Glass Transition Temp	Not conducted as the notified polymer is a liquid.
Density	990 kg/m ³
Water Solubility	The notifier states that the notified polymer forms a separate phase when added to water, and cannot be measured in the aqueous phase. Water solubility is expected to be very low (in the low mg/L range) because the notified polymer is a polyester with limited hydrophilic functionality.
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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	1	1.5	2	3	5

Use

The notified polymer will be used as a component in personal care products at concentrations up to 50%.

The notified polymer is used to provide gloss and will be used in products such as shampoos, conditioner, skin creams, lipsticks and lip-glosses and will be reformulated into such products within Australia.

Mode of Introduction and Disposal

The neat notified polymer will be imported in 16 kg containers or 100 kg drums by air or sea freight through Sydney or Melbourne.

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.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Eye irritation – The MatTek Corporation EpiOcular Tissue Model <i>In Vitro</i> Toxicity Testing System	non-irritating at a concentration of 10%	no	In house method
Skin sensitisation – Human repeat insult patch test.	no evidence of sensitisation and irritation	yes	In house method
Genotoxicity – bacterial reverse mutation	non mutagenic	no	In house method

One subject out of the 53 that completed the human repeat insult patch test showed barely perceptible erythema after the first of 9 applications. No further signs of irritation were seen in this or any other of the test subjects. Only 53 subjects were tested, which makes it unlikely that a sensitisation reaction would be detected. However, given the size of the polymer and the lack of structural alerts sensitisation would not be expected.

All results were indicative of low hazard.

Occupational Health and Safety Risk Assessment

Reformulation

Dermal and ocular exposure can occur during the reformulation of the notified polymer into cosmetic products. However, exposure to significant amounts of the notified polymer will be limited by engineering controls and the use of personal protective equipment, including impermeable gloves, eye protection and coveralls.

End use

Exposure of beauticians and hairdressers to the notified polymer at concentrations up to 50% could occur during final application of the cosmetic products to their clients. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible. PPE is not expected to be worn, however good hygiene practices are expected to be in place.

Although exposure to the notified polymer could occur during reformulation and end use, the risk to workers is not considered to be unacceptable due to the intrinsic low hazard of the notified polymer.

Public Health Risk Assessment

The general public will be repeatedly exposed to the notified polymer at concentrations up to 50% via a number of different consumer products. Exposure to the notified polymer will vary depending on individual use patterns.

Although the public will be exposed to the notified polymer during use of personal care products, the risk to public health is not considered to be unacceptable due to the intrinsic low hazard of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

Environmental Risk Assessment

The notified polymer is expected to be washed to sewer as an inescapable consequence of its use in personal care products. Based on its structure, significant removal can be expected during sewage treatment through sorption to sludge, with some biodegradation also likely to occur. The notified polymer would be expected to partition to sediment and biodegrade if released to receiving waters in treated effluent. Bioaccumulation would be precluded by the molecular weight. If released to aquatic environments, the notified polymer is expected to remain well below concentrations that could be harmful to aquatic life as polymers of this nature are of low concern to the aquatic environment. Therefore, 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 its low water solubility 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.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from as a component in personal care 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 notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.