

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Oleocraft LP-20-PA-(MV) - (INCI Name: Polyamide-8)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of the Environment.

This Public Report is 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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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1319	Croda Singapore Pte Ltd trading as Croda Australia	Oleocraft LP-20-PA-(MV) (INCI Name: Polyamide-8)	No	< 7 tonnes per annum	Cosmetic ingredient

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- 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 (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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 a cosmetic ingredient, 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 notified polymer 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 (M)SDS of the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Croda Singapore Pte Ltd trading as Croda Australia (ABN: 34 088 345 457)
Suite 102, Level I, 447 Victoria Street,
Wetherill Park, NSW 2164

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities and use details.

2. IDENTITY OF POLYMER

Marketing Name(s)

Oleocraft LP-20-PA-(MV)
INCI Name: Polyamide-8

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 Da

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

<i>Criterion</i>	<i>Criterion met</i>
The notified polymer meets the PLC criteria.	

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Light yellow pastilles
Melting Point/Glass Transition Temp	75-79 °C
Density	Not determined
Water Solubility	Expected to be insoluble based on hydrophobic structure
Dissociation Constant	Contains no dissociable functionalities
Particle Size	Not determined
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	<7	<7	<7	<7	<7

Use

The notified polymer will be used as a cosmetic ingredient. It will be imported at 100% concentration into Australia for reformulation into personal care products including leave on products and colour cosmetics at up to 30% concentration.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral (summary only, analogue)	LD50 > 5000 mg/kg bw	no	OECD TG 401 OECD TG 423
Rabbit, skin irritation at 47.1% (summary only, analogue)	non-irritating	no	OECD TG 404
Human, skin irritation (notified polymer at 7%)	non-irritating	no	Single application Patch Test
Rabbit, eye irritation (summary only, analogue)	slightly irritating	yes	OECD TG 405
<i>In vitro</i> , eye irritation (notified polymer at 7%)	practically non irritating	–	HET-CAM
Human, skin sensitisation (notified polymer at 30%)	no evidence of sensitisation*	no	Repeat Insult Patch test

* During induction, isolated instances of slight erythema were noted, however no effects were seen on challenge and the study authors considered that these effects were not indicative of irritation or sensitisation.

Occupational Health and Safety Risk Assessment

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. The risk of the notified polymer to occupational and public health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

Public Health and Safety Risk Assessment

The public may be exposed during use of personal care and cosmetic products containing the notified polymer at up to 30%. However, given the assumed low hazard, the risk posed by exposure to the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

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

The notified polymer will be imported neat into Australia for local reformulation into a variety of personal care products and cosmetic formulations. Release of the notified polymer during reformulation in Australia is expected to be limited to accidental spills or leaks and residue in import containers (estimated by the notifier to be $\leq 1\%$ of the total import volume, or up to 70 kg). These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

Based on its use in personal care products and cosmetics, it is expected that the majority of the notified polymer will be released to the aquatic compartment through sewers during use. Under a worst case scenario, it is assumed that 100% of the notified polymer will be washed into sewers. The resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated at

4.24 µg/L [PEC river = 19.18 kg notified polymer/day ÷ (200 L/person/day × 22.613 million people) × 1 (dilution factor)]. The PEC is below the EC50 for algae of the most toxic polymers (EC50 > 1 mg/L). In sewage treatment processes, very little of the notified polymer is expected to partition to the supernatant water, due to its high molecular weight and low solubility in water. Based on its high molecular weight and low water solubility, the notified polymer is not expected to cross biological membranes, and is therefore unlikely to bioaccumulate.

All wastes including container residues are expected to be disposed of to landfill. Based on its high molecular weight and chemical structure, the notified polymer is not expected to be readily biodegradable. In both surface waters and landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

Therefore, based on its assumed low hazard, the notified polymer is not considered to pose an unreasonable risk to the environment.