

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Acudyne DHR

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government 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 Australian Government Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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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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/1002	1) Rohm & Haas Australia Pty Ltd 2) Capitol Ingredients Australia Pty Ltd 3) Dow Chemical Australia Ltd	Polymer in Acudyne DHR	No	≤30 tonnes per annum	Component of hairstyling products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

The notified polymer is not considered to pose an unreasonable risk at up to 5% concentration in hairstyling products, provided that measures are in place to avoid prolonged, overexposure of workers and the public to aerosol spray products.

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

- Employers should implement the following engineering controls to minimise occupational exposure during aerosol spray applications of products containing the notified polymer:
 - Ventilation system
- Employers should implement the following safe work practices to minimise occupational exposure during aerosol spray applications of products containing the notified polymer:
 - Avoid inhalation of aerosol
- 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.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Aerosol spray products containing the notified polymer should carry the following safety directions (or similar) on the label:
 - Spray only in well ventilated areas
 - Avoid inhalation of aerosol

Disposal

- The notified polymer should be disposed of to landfill.

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- 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.
 - the notified polymer is intended for use in cosmetic aerosol products at >5% concentration.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of hairstyling 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 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 MSDS of a product containing the notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS**1. APPLICANT AND NOTIFICATION DETAILS****Applicants**

Rohm & Haas Australia Pty Ltd (ABN: 29 004 513 188)
Level 4, 969 Burke Road
Camberwell, VIC 3124

Capitol Ingredients Australia Pty Ltd (ABN: 30 055 147 567)
Unit 9, 7 Meridian Place
Bella Vista, NSW 2153

Dow Chemical Australia Ltd (ABN: 72 000 264 979)
541-583 Kororoit Road

Altona, VIC 3018

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, import volume and identity of analogue polymer.

2. IDENTITY OF POLYMER

Marketing Name(s)

Acudyne DHR (<50% notified polymer)

Molecular Weight

Number Average Molecular Weight (Mn) >10,000 Da

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	White milky liquid*
Melting Point/Glass Transition Temp	Not determined as the polymer is not isolated from solution
Density	1100 kg/m ³ at 25 °C*
Water Solubility	Not determined. The notifier advised that the solubility is pH dependent, being insoluble below pH 4 and soluble above pH 7.5.
Dissociation Constant	The notified polymer contains carboxylic acid functionality and is expected to have typical acidity (pK _a ~4-5)
Reactivity	The notified polymer contains hydrolysable functionality, but is not expected to hydrolyse under environmental pH conditions.
Degradation Products	None under normal conditions of use
*Acudyne DHR containing <50% notified polymer	

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	1-3	3-10	3-10	3-10	10-30

Use

The notified polymer will not be manufactured in Australia.

The notified polymer will be imported into Australia as a component of finished hairstyling products (at ≤5% concentration) or as a component of Acudyne DHR (at <50% concentration) for reformulation into hairstyling products. The notified polymer will be used as a hair fixative in leave-on hairstyling products, such as hair sprays, mousses and gels, at ≤5% 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, which were conducted on the notified polymer (as imported, at <50% concentration) or analogue polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral ⁽¹⁾	LD50 >5000 mg/kg bw	no	OECD TG 425
2. Rat, acute dermal ⁽¹⁾	LD50 >5000 mg/kg bw	no	OECD TG 402
4. Rabbit, skin irritation ⁽¹⁾	slightly irritating	yes (slight erythema recorded at 1 and 24 hours after patch removal. Skin appeared normal after 48 hours).	OECD TG 404
5. Rabbit, eye irritation ⁽¹⁾	slightly irritating	yes (slight conjunctival irritation noted in treated eyes 1- and 24-hours post instillation. Eyes appeared normal after 48 hours).	OECD TG 405
6. Skin sensitisation – Human repeat insult patch study ⁽¹⁾	no evidence of sensitisation.	no	-
7. Rat, inhalation repeat dose toxicity - 90 days ⁽²⁾	NOEL = 1.0 mg/m ³ NOAEL = 7.3 mg/m ³ ⁽³⁾	Yes ⁽⁴⁾	OECD TG 413
8. Genotoxicity - bacterial reverse mutation ⁽¹⁾	non mutagenic	No	OECD TG 471

(1) Study conducted on the imported product containing <50% notified polymer.

(2) Study conducted on an analogue of the notified polymer.

(3) NOAEL determined by the study authors.

(4) Effects discussed in text below.

The imported product containing the notified polymer (at <50% concentration) was determined to be slightly irritating to the skin and eyes of rabbits. However, the effects observed in the skin and eye irritation studies did not warrant classification of the test substance as an irritant.

There were no mortalities in a 90-day repeat dose inhalation study conducted on an analogue of the notified polymer (mean respirable fractions of the aerosols ranged from 77-89%; the water solubility of the analogue polymer is not known). Treatment-related effects were limited to the high (73.2 mg/m³) and mid (7.3 mg/m³) dose groups, though for those effects observed in the mid dose group, they were deemed by the study authors not to be adverse. Treatment related effects included increased lung weight, changes in the white blood cell parameters, increases in alveolar macrophages (accompanied by neutrophils in the high dose group) and slight hyperplasia of the mediastinal lymph nodes. Following a 14-week recovery period, the effects noted in the lungs of the animals of the high dose group included increased alveolar macrophages, minimal alveolitis and minimal bronchiolar and alveolar epithelial hyperplasia. In addition, it was noted that the mediastinal lymph nodes were less enlarged/hyperplastic than those examined at the completion of the exposure period. The study authors note that the changes observed suggest an impairment of macrophage clearance.

The significance of these lung-overload type findings to the notified polymer is uncertain. However, based on this study and given that high molecular weight polymers (Mn >10,000 Da, particularly

polymers with low water solubility) do present a concern for potential lung damage following respiration of particles, the possibility of similar lung overloading effects cannot be excluded if there is inhalation exposure to aerosols with particle sizes in the respirable range.

The notified polymer is intended to be used in a range of hairstyling products at $\leq 5\%$ concentration, including aerosol hair sprays. The primary risk to human health associated with use of products containing the notified polymer will be due to the potential for lung overloading effects following inhalation of aerosols from hairsprays. The potential for the formation of respirable particles is considered to be lower for pump hairsprays and inhalation exposure is not expected during use of non-spray products.

The water solubility of the notified polymer is reported to vary with pH and this is likely to affect the potential for lung overloading. If the notified polymer is inhaled at low levels and/or infrequently, it is likely to be cleared from the lungs. However, high level and/or frequent exposure may result in lung overloading effects, though the level of exposure in humans that would result in these effects and the severity of these effects is uncertain. The degree of exposure of workers (namely, hairdressers) and the public to hairsprays containing the polymer is likely to vary greatly depending on the amount and frequency of individual application and the spray environment (e.g. room size and degree of ventilation).

Therefore, the risk to the health of workers and the public from use of the notified polymer in hairstyling products at $\leq 5\%$ concentration is not considered to be unreasonable provided that measures to minimise exposure during aerosol spray applications are in place. Such measures include that users be directed to only apply hairsprays in well ventilated areas and to avoid inhalation of the spray contents.

ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. However, the notified polymer is an anionic polymer, to which algae is expected to be the most sensitive species. 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, which may apply to the notified polymer. However, the toxicity of the notified polymer to algae is likely to be reduced due to the pendant position of the acid groups and dilution of the chelating monomer with non-chelating monomers. In addition, the toxicity to algae is likely to be further reduced due to the presence of calcium ions in environmental waters, which will bind to the functional groups.

The majority of the notified polymer will be released to sewage treatment plants, although up to 3% is expected to be disposed of to landfill as residues in import and end-use cosmetic containers. Under a worst case scenario it will be assumed that 100% of the notified polymer will be washed into sewers. Assuming 75% of the notified polymer will be removed via absorption to sludge in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated as $4.54 \mu\text{g/L}$ [$\text{PEC}_{\text{river}} = 82.19 \text{ kg notified polymer/day} \div (200 \text{ L/person/day} \times 22.613 \text{ million people}) \times 1 \text{ (dilution factor)}$]. The PEC is well below the EC_{50} for algae of the most toxic anionic polymers ($\text{EC}_{50} > 1 \text{ mg/L}$).

The notified polymer is not expected to cross biological membranes due to its high molecular weight and it is therefore not expected to bioaccumulate. It is expected to eventually degrade by abiotic and biotic processes to form water and oxides of carbon.

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