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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Aculyn 38 (Acrylates/Vinyl Neodecanoate Crosspolymer)

This Self Assessment has been compiled by the applicant and adopted by NICNAS 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), administered by the Department of Health and Ageing and the Department of the Environment and Heritage has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

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Director
NICNAS

Part 2 –PLC Self Assessment

Aculyn 38 (Acrylates/Vinyl Neodecanoate Crosspolymer)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Rohm and Haas Australia Pty. Ltd. (ABN 29 004 513 188)
4th Floor, 969 Burke Road
Camberwell, VIC 3124

NOTIFICATION CATEGORY
Self Assessment: Polymer of Low Concern

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

NOTIFICATION IN OTHER COUNTRIES
None known

2. IDENTITY OF CHEMICAL

MARKETING NAME
Aculyn 38

OTHER NAME
Acrylates/Vinyl Neodecanoate Crosspolymer

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW)	>10000 Da

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
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	Milky, white liquid emulsion as imported.
Melting Point/Glass Transition Temp	Not applicable. The notified polymer will not be isolated from the solution.
Density	1,050 – 1,100 kg/m^3 at 25°C (imported emulsion).
Water Solubility	365 ppm at 37°C and pH 7 (OECD TG 105)
Dissociation Constant	The notified polymer has anionic groups expected to have typical acidity.
Particle size	The notified polymer will be imported in a liquid emulsion and will not be separated from the aqueous phase.
Reactivity	The notified polymer contains potentially hydrolysable groups but hydrolysis is not expected to occur in the environmental pH range of 4-9.
Degradation Products	None under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1	2	4	5	6

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will not be manufactured in Australia.
It will be imported as a 28% w/w aqueous emulsion called Aculyn 38.
Currently no customers have been established for the product. However, it is expected that up to 10 customers throughout Australia will be identified.

The imported Aculyn 38 product containing the notified polymer will be imported in 200 litre plastic drums. Upon arrival at ports in Sydney and/or Melbourne the notified polymer will be transported by road to the notifier's warehouse where it will be stored under cover until such time that it is transported to customers throughout Australia.

Reformulation

At the reformulator, the product will be formulated into personal care products. These products will contain up to 3.0% w/w of the notified polymer.

Typically during reformulation, the notified polymer will be manually weighed and then poured directly into a blending vessel with the aid of a mechanical lifting device. Once blended with other ingredients and converted into the finished product, it will be packaged into a variety of plastic containers of up to 1 litre capacity for sale to both beauty salons and the general public.

Use

The notified polymer is intended to be used as a thickener and/or stabilizer and/or suspending agent in hair shampoo, bodywash, facial wash or other personal care cleansing products.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Transport and warehousing workers may come into dermal and ocular contact with the notified polymer through accidental leaks and spillages of the drums and containers.

Typically, during reformulation, workers will manually weigh and transfer the polymer solution to the mixing vessel. Exposure from the notified polymer to these workers can occur by either dermal or ocular routes, however significant exposure will be limited due to the workplace practices and personal protective equipment used. It is expected that workers will wear impermeable gloves, eye protection and coveralls.

Typically during filling of personal care product packaging, the product will be pumped from holding tanks to the automated filling equipment. Exposure to the notified polymer to these workers can occur during filling line operation and cleaning. Exposure will be by either dermal or ocular routes, however significant exposure will be limited due to the workplace practices and personal protective equipment used. It is expected that filling line workers will wear impermeable gloves, eye protection and coveralls.

Some personal care products will be used in beauty salons where workers will come into contact with the notified polymer via dermal or ocular routes during application of the end use product.

PUBLIC EXPOSURE

Approximately 90% of the personal care products (containing <3% of the notified polymer) will be used by the public.

Exposure will be by either dermal or ocular routes. The vast majority will be dermal exposure due to application of the product. These personal care cleansing products will usually be wiped or rinsed off shortly after application.

6.2. Toxicological Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Under the conditions of the occupational settings described, the notified polymer is not expected to pose an unacceptable risk to workers, based on the assumed low hazard of the notified polymer and low exposure as well as the personal protective equipment used by workers involved with reformulation.

PUBLIC HEALTH

Members of the public who use personal care products containing the notified polymer will make dermal contact and possible accidental ocular contact with the notified polymer. However, the risk to public health is not expected to be unacceptable given the assumed low hazard of the notified polymer and its low concentration in personal care products (<3%).

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Release to the environment during shipping, transport and warehousing will only occur through accidental spills or leaks from the drums and end use containers.

During formulation and packaging, spills are expected to be minimal. When spills occur, they will be contained by bunding, collected with absorbent material and sent to a licensed off site waste disposal centre. Empty drums from import will be sent to drum reconditioners.

Cleaning of manufacturing and packaging equipment will be performed by flushing with water. Typically, cleaning water and product residues will be transferred to the on site waste treatment facility where solids will be precipitated and later disposed of to a licensed waste landfill site.

The total amount of waste polymer produced during reformulation and packaging due to spills, drum residues and cleaning is expected to be approximately 3% or 180 kg of the maximum import volume.

Approximately 5% (or 300 kg) of the notified polymer will remain as residues in consumer packaging and will be disposed of to landfill via domestic waste.

The remainder (92% or 5,520 kg) of the notified polymer will be released to sewerage systems throughout Australia through public use for the washing of skin and hair.

ENVIRONMENTAL FATE

The notified polymer is expected to be hydrolytically stable and to not be readily biodegradable. Due to its high molecular weight and hence inability to cross biological membranes, the notified polymer is not expected to bioaccumulate.

The notified polymer has low solubility in water and will not be readily mobile in aquatic and terrestrial compartments. Due to its anionic nature, the notified chemical

is likely to be further immobilised via adsorption onto soil particles and sediments in landfill and sewage treatment plants, eventually degrading through biotic and abiotic processes to form oxides of carbon.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted.
The notified polymer contains acid groups. Generally, this type of polyanionic polymer will not be toxic to fish or daphnids with a LC_{50} >100 mg/L. However, anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The most toxic form is when the acid is on alternating carbons of the polymer backbone with the 96 hr EC_{50} for green algae ranging from 3.13 to 37.4 mg/L with a geometric mean of 8.6 mg/L. (Boethling and Nabholz, 1997). Thus, with a safety factor of 1000, the resultant PNEC (LC_{50} of most sensitive species/safety factor) is 8.6 µg/L.

7.3. Environmental Risk Assessment

All of the imported notified polymer will eventually be released into the environment. Up to 480 kg will be released to landfill via spills, cleaning equipment and packaging residues.
The remainder, or up to 5,520 kg, will be discharged into sewerage systems after washing hair and skin.

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

Assuming that 92% of the notified polymer is eventually released to the sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is 15.1 kg/day using the maximum import volume of 6 tonnes/annum.

Based on a national population of 20.5 million and a daily water consumption of 200 litres/day the Predicted Environmental Concentration (PEC) is calculated as follows:

$$PEC_{sewer} = \frac{(5{,}520 \times 1 \times 10^6)\ mg}{20{,}500{,}000 \times 200 \times 365\ L}$$
$$= 0.00368\ mg/L$$
$$= 3.68\ \mu g/L$$

When released to receiving waters (ocean) the concentration is generally understood to be reduced by a further factor of at least 10. However, as products containing the notified polymer will be used nationwide, no further dilution on release to receiving waters will be assumed as a worst-case estimate.

Using the above PNEC estimate and the calculated PEC, a risk quotient (RQ = PEC/PNEC) can be estimated, RQ = 3.68/8.6 = 0.43.
With a RQ less than 1 and based on the proposed use pattern of the notified polymer,

the amount being imported, and the nationwide use of the products and subsequent diffuse release, it is not expected to pose an unacceptable risk to the health of aquatic life.
The above RQ is based on conservative assumptions of volume introduced and toxicity, and undiluted total release to inland waters. It is likely that a further reduction in the RQ will occur due to adsorption of the notified polymer to sludge and sediments in the aquatic environment. The algae toxicity is likely to be further reduced due to the presence of calcium ions in natural waters, which will bind to the acidic functional groups (Boethling and Nabholz, 1997).

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety and Public Health

When used in the proposed manner, and under the conditions of the occupational settings the notified polymer is not considered to pose an unacceptable risk to workers and public health.

8.3. Level of Concern for the Environment

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

9. 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 by drying and sending to landfill.

Emergency procedures

- Spills/release of the notified polymer should be handled by containment and absorption by inert material.

10.1. 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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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 introduced in powder form.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of hair shampoo, bodywash, facial wash or other personal care cleansing products;
- the amount of polymer being introduced has increased from 6 tonnes per annum, or is likely to increase, significantly;
- if the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the 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.

10.2. 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.