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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Acusol 448

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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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Rohm and Haas Australia Pty Ltd (ABN 29 004 513 188)
969 Burke Road
CAMBERWELL VIC 3124

Ecolab Pty Ltd (ABN 59 000 449 990)
6 Hudson Avenue
CASTLE HILL NSW 2154

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name, Molecular formula, Structural formula, Spectral data, Polymer constituents, Residual monomers, Molecular weight.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point, Density, Vapour pressure, Water solubility, Hydrolysis as a function of pH, Partition coefficient, Adsorption/desorption, Dissociation constant, Flash point, Flammability limits, Autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in Acusol 448
Component of Stonemedic SCS Stone Cleaner Solution

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is not isolated from solution. Limited physicochemical data has been provided for Acusol 448 containing 50% notified polymer.

APPEARANCE AT 20°C AND 101.3 kPa:
Clear, colourless aqueous solution (for Acusol 448 containing 50% of notified polymer)

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Will only be imported as an aqueous solution.
Density	1000-1200 kg/m^3 at 20°C	MSDS (for Acusol 448 containing 50% notified polymer).
Vapour Pressure	Not determined	Expected to be low based on molecular weight.
Water Solubility	> 500 g/L at 20°C	Based on Acusol 448 containing 50% w/w notified polymer in water.
Hydrolysis as a Function of pH	Not determined	Not expected to readily hydrolyse in the environmental pH range of 4–9, based on its structure.
Partition Coefficient (n-octanol/water)	Not determined	Expected to largely partition to water based on water solubility. Measurement of this parameter would be confounded by the surface activity of the notified polymer.
Adsorption/Desorption	Not determined	Expected to sorb to soils and sediment because of its polyanionic nature.
Dissociation Constant	pKa < 5	Estimated based on presence of acid groups.
Particle Size	Not determined	Will only be imported as an aqueous solution.
Flash Point	Not determined	Will only be imported as an aqueous solution.
Flammability	Not determined	Not isolated from aqueous solution.
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores

DISCUSSION OF PROPERTIES
The notified polymer is expected to have a low vapour pressure and to be highly water-soluble.

Reactivity
The notified polymer is expected to be stable under normal storage and handling conditions.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The product Acusol 448 containing the notified polymer at a concentration of 50% (~70% of import volume) will be imported by Rohm and Haas Australia Pty Ltd for formulation into a variety of domestic and industrial cleaners and detergents. The remainder of the notified polymer (~30% of the import volume) will be imported by Ecolab Pty Ltd as a component of the product Stonemedic SCS Stone Cleaner Solution at a concentration of < 1%. Stonemedic SCS Stone Cleaner will be used as an industrial floor cleaner.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	6	10	15	20	30

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Reformulations will be conducted at up to 20 sites throughout Australia.

TRANSPORTATION AND PACKAGING
The Acusol 448 product containing the notified polymer (at 50%) will be imported in 200 L steel drums and will be transported from the wharf by road to the notifiers warehouse before being distributed by road to reformulators throughout Australia. The notified polymer will be reformulated into a variety of cleaners and detergents and packed into plastic containers ranging from 0.5 to 20 L. These products will be distributed by road to industrial sites and retail stores.

The industrial cleaner product containing the notified polymer (at < 1%) will be imported in 20 L plastic cubes. The product will be transported by road from the wharf to the notifiers warehouse before being distributed by road to industrial end users.

USE
The notified polymer will be used in domestic and industrial cleaners and detergents, including solid and liquid laundry detergents, dishwashing detergents, and car and floor cleaners at concentrations of < 10%. Typically the products will be diluted in the ratio of one part cleaner to 100 parts water before use and therefore the concentration during cleaning will be < 0.1%.

OPERATION DESCRIPTION
The imported industrial cleaner product containing < 1% of the notified polymer will not be reformulated.

Formulation of detergents and cleaners
Acusol 448 containing the notified polymer (at 50%) will be manually transferred from the imported drums to a blending vessel where it will be mixed with other ingredients to form the finished products. The manual transfer will involve inserting a tap into the drum and then lifting and decanting the contents with the aid of a mechanical drum lifting device or forklift.

At the end of the blending process, samples will be taken for quality control using a plastic cup or pipette. The finished products (containing up to 10% of the notified polymer) will then be transferred from the blending vessel to a variety of different sized packaging containers and types. Different types of filling techniques will be employed ranging from full manual decanting to fully automated processes. Some of the packed containers will be further packed into cardboard boxes. Pallets of packed product will then be stored before distribution to customers.

The blending vessel and filling lines will be cleaned after the formulation of each batch by flushing the system with water.

End use
The final formulated products containing the notified polymer (at up to 10%) will be used in industrial and institutional settings as well as by the general public. Applications include car and floor cleaners, and laundry and dishwashing detergents. Typically the products will be diluted in the ratio of one part cleaner to 100 parts water before use and therefore the concentration during cleaning will be < 0.1%.

The industrial cleaner product imported containing < 1% of the notified polymer will be used as supplied by professional applicators for cleaning floors.

Cleaning products are generally applied with a cloth or sponge, by mop or brush or by spray followed by wiping.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Dockside and transport	60	4	12
Warehouse	40	2	24
Process operators	40	4	12
Quality control	20	1	12
Filling and packing	10	4	12
End-users (cleaners)	> 3000	1-8	365

EXPOSURE DETAILS

Transport and storage
Dockside, transport and warehouse workers will not be exposed to the notified polymer except in the unlikely event of an accident.

Formulation
Dermal and ocular exposure to the notified polymer (at 50%) by process operators may occur during transfer of Acusol 448 from the drums to the blending vessel. Dermal and ocular exposure to the notified polymer (at up to 10%) may also occur during blending, when taking quality control samples, during packing-off the finished product and cleaning of blending vessel, transfer and packing lines.

Laboratory technicians may be potentially exposed to the notified polymer (at up to 10%) when sampling and testing formulation samples. However, they will handle only small quantities and will wear appropriate personal protective equipment.

It is stated by the notifier that all process workers are expected to wear personal protective equipment (coveralls, safety goggles and gloves) to limit exposure.

End use
Exposure to the notified polymer by professional cleaners is expected to be widespread, frequent and extensive. Dermal and ocular exposure to the notified polymer (at < 10%) may occur during dilution with water and when industrial cleaning workers apply the cleaners and detergents containing the notified polymer (at up to 1%). Inhalation of aerosols could occur where application is by spray. The level of exposure will vary depending on the method of application and work practices employed.

6.1.2. Public exposure
Exposure by the public to the notified polymer (at up to 10%) is expected to be identical or of a lesser extent to that experienced by professional cleaners.

There is also potential for dermal exposure by the public through contact with cleaned surfaces with products containing the notified polymer. However, exposure would be low because contact is only intermittent and residues of the notified polymer should have been largely removed during cleaning.

6.2. Human health effects assessment

No toxicity data were submitted.

General toxicity
Although there is a high percentage of low molecular weight species (MW < 500 Da) present, transport across biological membranes is expected to be limited given the high water solubility and polar character of the notified polymer.

Irritation and Sensitisation

The notified polymer contains carboxylic acid groups that are structural alerts for skin irritation (Hulzebos, 2005). However, given the expected limited potential for dermal uptake of the notified polymer, the potential for skin irritancy is considered to be at most slight.

Based on lack of structural alerts for sensitisation, high water solubility and high molecular weight, skin sensitisation is not expected.

Health hazard classification
Based on the available data it is not possible to classify the notified polymer as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Due to the limited available information, the hazard of the notified polymer is uncertain. However, based on structural alerts and properties of the notified polymer, systemic toxicity is not expected at the levels of exposure but slight irritancy is possible.

Workers most at risk of irritation are process workers handling the product Acusol 448 containing the notified polymer at a concentration of 50%, particularly when transferring to the blending vessels. This risk should be minimised through the stated use of PPE. The risk to all other workers including professional cleaners is expected to be low, given they will only handle products containing the notified polymer at a concentration up to 10% (and < 1% as applied), significantly below the stated cut-off level of 20% for irritation (NOHSC, 2004).

Overall, the risk to workers of the notified polymer is not considered to be unacceptable.

6.3.2. Public health
Given the public will only handle products containing the notified polymer at a concentration up to 10% (and < 1% as applied), the risk of irritancy to the notified polymer is considered to be low even with the consideration that the public may or may not wear appropriate PPE.

Overall, the risk to public health of the notified polymer is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The quantity of notified polymer in Acusol 448 (70% of the import volume) will be reformulated at up to 20 sites throughout Australia. Approximately 0.5% is expected to remain as residues in "empty" drums. These drums will be sent to drum reconditioners, where the residue is expected to be precipitated in waste treatment works sludge that will be sent to licensed waste landfill. An estimated further 3% of the notified polymer will be lost to spills and equipment cleaning water. As a worst case scenario, approximately 50% of this will go to licensed waste landfill as dried polymer and the remainder will enter the sewer. Therefore, approximately 420 kg per annum will be released to licensed waste landfill sites and 315 kg per annum will be lost to the sewer.

RELEASE OF CHEMICAL FROM USE
As a result of using detergents and cleaners, it is expected that the vast majority of the notified polymer will be released to the sewage system.

RELEASE OF CHEMICAL FROM DISPOSAL
Approximately 1% of the notified polymer will remain as residues in end use containers. These containers will be disposed of to landfill or recycled.
As a result of using detergents and cleaners, it is expected that the vast majority of the used notified polymer will be disposed of to the sewage system.

7.1.2 Environmental fate

No environmental fate data were submitted, but the environmental fate of the notified polymer can be predicted by analogy with other detergent chemicals of this class (CETOX, 2001). As a polycarboxylate, the notified polymer is expected to be removed during sewage treatment by sorption onto sludge. The notified polymer is not expected to be readily biodegradable. Residues that enter waterways when sewage effluent is discharged will tend to partition to sediment and suspended solids and slowly degrade. Residues in soils that have been amended with biosolids are expected to remain immobile and slowly degrade. The notified polymer is unlikely to bioaccumulate because the molecular weight exceeds 1000. A proportion of the notified polymer has a molecular weight less than 1000 and could therefore be absorbed by fish, but significant bioaccumulation is not expected because of the water solubility.

7.1.3 Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration is calculated based on the worst-case scenario where all of the notified polymer (30 tonnes per annum) will be released to the sewer.

The details of the calculation based on these parameters are presented below:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	30,000	kg/year
Proportion expected to be released to sewer	1.0	
Annual quantity of chemical released to sewer	30,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	82.2	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.200	million
Removal within STP	0%	
Daily effluent production:	4,240	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	19.2	µg/L
PEC - Ocean:	1.92	µg/L

7.2. Environmental effects assessment

No ecotoxicity 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). The notified polymer does contain acid groups on alternating carbon atoms, thus there is potential for algae toxicity.

7.2.1 Predicted No-Effect Concentration

The Predicted No Effect Concentration (PNEC) was calculated using the LC50 for the most sensitive species (algae) and a conservative safety factor of 1000.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment			
LC50 for algae	8.6		mg/L
Assessment Factor	1000		
Mitigation Factor		1.00	
PNEC:	8.6		µg/L

7.3. Environmental risk assessment

Based on the above PEC and PNEC values, the following Risk Quotients (Qs) have been calculated:

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	19.2	8.6	2.23
Q - Ocean	1.92	8.6	0.22

A risk quotient less than 1 indicates that the intended use of the notified polymer is not expected to pose a risk to the health of marine life.

The risk quotient for receiving rivers of 2.23 is based on a worst-case scenario assuming that no polymer will be removed from water in STPs. However, the polyanionic nature of the notified polymer indicates that it will bind to soils and sediments and thus a portion of the notified polymer would be removed in STPs and further in receiving waters. Model data (CETOX, 2001) for a polyanionic polymer with much higher molecular weight than the notified polymer show substantial removal (90%) to sludge with only 2-3% retained in the supernatant. As the notified polymer has lower molecular weight, it will be assumed conservatively that up to 30% could be retained in the supernatant. Thus the PECs for fresh and marine waters can be reduced to 5.8 and 0.58, respectively. Risk quotients for both situations fall below unity, as tabulated below.

Revised Risk Quotients assuming part removal in STP

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	5.8	8.6	0.67
Q - Ocean	0.58	8.6	0.067

The algal 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). Therefore, the intended use of the notified polymer is not expected to pose a risk to the health of aquatic life.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. The notified polymer is classified as being toxic under the GHS classification scheme, based on the estimated Algae 96 h EC50 = 8.6 mg/L. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Acute hazards to the aquatic environment	2	Toxic to aquatic life

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
On the basis of the PEC/PNEC ratio 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

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the product Acusol 448:
  - Coveralls
  - Impermeable gloves
  - Safety goggles

  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 chemical 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 chemical should be disposed of by landfill.

Emergency procedures

- Spills or accidental release of the notified chemical 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 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 polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of domestic and industrial cleaners and detergents, or is likely to change significantly;
- the amount of chemical being introduced has increased from 30 tonnes per annum, or is likely to increase, significantly;
- if the chemical 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 products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

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