

File No: EX/181 (LTD/1587)
April 2012

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

PUBLIC REPORT

Polymer in Acusol 420N

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 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**Director
NICNAS**

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FULL PUBLIC REPORT

This assessment report is for an extension of original assessment certificate for Polymer in Acusol 420N. Based on the submission of new information by the extension notifier, some sections of the original assessment report for Rohm and Haas Australia Pty Ltd and Dow Chemical (Australia) Limited have been modified. These modifications have been made under the heading 'Extension Application' in the respective sections.

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
EX/181 (LTD/1587)	Miele Australia Pty Ltd	Polymer in Acusol 420N	ND	≤ 100 tonnes per annum	Component of dishwashing products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Risk assessment and recommendations relating to extension application

The proposed use, introduction volume and fate of the notified polymer will not change significantly under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environmental risk assessment and recommendations.

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 to landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical 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 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 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 polymer has changed from a component of dishwashing products or is likely to change significantly;
 - the amount of polymer being introduced has increased from 100 tonnes, or is likely to increase, significantly;
 - 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.

Material Safety Data Sheet

The MSDS of the product containing the notified polymer was provided by the notifier and reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Extension Application:

The applicant for the extension application has provided an MSDS of the product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

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

Dow Chemical (Australia) Limited (ABN 72 000 264 979)
541-583 Kororoit Creek Road

Altona VIC 3018

Applicant for an Extension of the Original Assessment Certificate

Miele Australia Pty Ltd
1 Gilbert Park Drive
Knoxfield VIC 3180

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

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, analytical data, polymer constituents, residual monomers, impurities, additives/adjuvants, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical properties.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Acusol 420N (containing the notified polymer at 30-60%)

Extension Application

Miele Care Collection Dishwashing Tabs (containing the notified polymer at 2.25%)

MOLECULAR WEIGHT

$M_n > 1,000$ Da

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 96%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear amber liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Will only be introduced as an aqueous solution.
Boiling Point	Not determined	Polymer with NAMW > 1,000 Da.
Density*	1400 kg/m ³	MSDS
Vapour Pressure	< 1.3x10 ⁻⁹ kPa	Estimated based on high molecular weight (US EPA, 2010)
Water Solubility	Not determined	Expected to be water soluble based on its chemical structure and use in an aqueous product at a concentration of up to 60%
Hydrolysis as a Function of pH	Not determined	The notified polymer does not contain any readily hydrolysable functionality and is therefore expected to be hydrolytically stable
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to water based on its anticipated high water solubility
Adsorption/Desorption	Not determined	The notified polymer is expected to be mobile in silos based on its high water solubility
Dissociation Constant	Not determined	The notified polymer is a salt which is

Flash Point	Not determined	expected to be dissociated in the environmental pH range (4-9)
Flammability	Not determined	Polymer with NAMW > 1,000 Da.
Autoignition Temperature	Not determined	Will only be introduced as an aqueous solution.
Explosive Properties	Not determined	Will only be introduced as an aqueous solution.
Oxidising Properties	Not determined	Not expected to have explosive properties based on structure.
		Not expected to have oxidative properties based on structure.

*For imported product containing the notified polymer in an aqueous solution at 30-60% concentration.

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to be stable under normal use conditions.

Dangerous Goods classification

Based on the submitted physico-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However, the data above do not address all Dangerous Goods endpoints. Therefore, consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as an aqueous solution at a concentration of 30-60%.

Extension Application

The notified polymer will be imported in formulated dishwasher tablets at a concentration of 2.25%.

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	< 50	< 50	< 50	< 100	< 100

Extension Application

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

PORT OF ENTRY

Melbourne by wharf

Extension Application

Melbourne, Sydney, Perth, South Australia and Queensland

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 215 kg lined steel drums or 1000 kg IBC. It will be transported by road from the port to the notifier's warehouse and from there it will be transported to the customers' sites for reformulation. The reformulated product will be supplied in consumer type packaging such as 300 ml to 2 L plastic bottles for liquid products and as 20 gram tablets packed in plastic/cardboard combination packs for solid preparations.

Extension Application

Dishwasher tablets containing the notified polymer (2.25% concentration) will be contained in water soluble wrappers and packaged in cartons. The cartons will be transported within Australia by road.

USE

The notified polymer will be used as a dispersant for auto dishwashing tablets and liquid and powder laundry products at a concentration up to 3%.

Extension Application

The notified polymer will be used in dishwashing tablets in domestic dishwashers at a concentration of 2.25%.

OPERATION DESCRIPTION

Reformulation (liquids)

The reformulation process will involve a typical liquid blending operation. Both batch and continuous blending processes are used to manufacture liquid and gel cleaning products. The process is fully automated, enclosed and banded.

The imported product containing the notified polymer at up to 60% will be pumped from the import containers into closed holding tanks. From the holding tanks the imported product containing the notified polymer at up to 60% will be dosed into the blending tank and mixed with other ingredients to form the finished products. The finished product containers, typically, 300 mL to 2 L plastic bottles with screw cap, will be automatically filled and packaged into cardboard cartons for transport to retailers. The concentration of the notified polymer in the finished products will be up to 3%.

Reformulation (solids)

The imported product containing the notified polymer at 60% will be blended with other ingredients within a mixer to form a slurry which will be pumped via pipework to a rotary tablet press. The mixer and the tablet press are enclosed to avoid dust generation. The manufactured tablets containing the notified polymer at up to 3% then travel on a conveyor belt to a packaging machine.

Retail

After the notified polymer has been incorporated into the laundry detergent or dish washing tablets, the containers will then be put into shippers and transported to retail outlets nationally. At the retail outlet, the shippers will be unloaded and the products placed on the shelves for sale.

Professional laundry workers

Laundry workers will open the formulated laundry product containers and manually measure out the required volume of the product (typically 50 mL). This will be done by either using the cap of the container, which also serves as the measuring device, or into a plastic measuring/dispensing cup prior to adding it into the washing machine. These workers will also remove washed cloths from the washing machine. At this stage the notified polymer has been rinsed off from the cloths.

Professional workers are unlikely to use dishwashing detergent tablets.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Waterside workers	2-3	Once a month
Transport drivers to customers	3-4	200
Transport drivers interstate	12	40-50
Warehouse workers	1	200
Process workers/site	8	200
Retail workers	5-8	200
Professionals Laundry workers	5-8	200

EXPOSURE DETAILS

Transport and Warehousing

During transportation, warehousing, and distribution, exposure to the notified polymer is not expected, except

in the unlikely event of an accident where the packaging is damaged.

Reformulation

Dermal and possible ocular exposure to the notified polymer at concentrations up to 60% may occur when connecting and disconnecting transfer lines. Negligible exposure to the notified polymer is expected at other times during the reformulation process as blending and packaging will occur in enclosed systems and will be fully automated. Workers involved in the reformulation process are expected to wear impermeable gloves, eye protection and protective clothing to minimise exposure.

Inhalation exposure is not expected given the estimated low vapour pressure ($< 1.3 \times 10^{-9}$ kPa) of the notified polymer. In addition, blending and packaging facilities are expected to be well ventilated and generally will also use local exhaust ventilation.

Use - Professional Laundry Workers

Laundry workers may be exposed to the finished products containing up to 3% of the notified polymer. The exposure may result during measuring and dispensing of the laundry product. The most likely route of exposure will be dermal. It is recommended that workers wear gloves during the dispensing operations.

6.1.2. Public Exposure

The public may be exposed to the finished products containing up to 3% of the notified polymer. The exposure may result during measuring and dispensing of the laundry product or when handling the dishwashing tablets. The most likely route of exposure will be dermal.

Extension application

Public exposure to the notified polymer in dishwashing tablets (up to 2.25% concentration) is expected to be mainly dermal. Exposure is expected to be minimal as the dishwashing tablets will be contained in water soluble packaging and direct handling of the tablet will not occur except when the packaging is breached.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

Given the high molecular weight (NAMW > 1000 Da), the notified polymer is unlikely to cross biological membranes and cause systemic toxicity. In addition, the notified polymer is devoid of any structural alerts which may indicate potential toxicity. Therefore, the low molecular species of this polymer are not expected to cause toxicity.

Health hazard classification

Based on the limited data provided the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer is expected to be of low hazard based on the absence of structural alerts. In addition, given the reformulation process is mostly automated and enclosed and workers are expected to use PPE, and the low concentration in the finished products, the potential for exposure is expected to be limited.

Therefore, the risk to workers associated with the use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

Given the low concentration of the notified polymer in the consumer products (up to 3%) and expected low hazard, the risk to the public from use of the notified polymer is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured in Australia. During reformulation and transportation, release of the notified polymer to the environment could result from accidental spills and leaks and during handling of the polymer. In addition release could result during reformulation processes from disposal of washings when transfer lines and blending tanks are flushed out. The above releases are expected to total 0.5% of the annual import volume and are expected to be released to sewer via onsite waste water treatment plants.

RELEASE OF CHEMICAL FROM USE

The majority of the notified chemical is expected to be released to sewers nationwide as a result of its use in dishwashing tablets and in liquid and powder laundry products.

RELEASE OF CHEMICAL FROM DISPOSAL

It is expected that minor amounts of the product containing the notified chemical will remain as residues in empty end-use containers. The containers are expected to be disposed of through domestic garbage disposal and will enter landfill or be recycled.

7.1.2. Environmental Fate

No fate data were provided for the notified polymer. The majority of the notified polymer is expected to be released to sewage treatment plants (STPs). Based on its molecular weight and high water solubility, no removal of the notified polymer from STP effluent is anticipated (Boethling & Nahbolz, 1997) and the notified polymer is expected to remain in the water column. Notified polymer reaching surface waters via treated STP effluent is expected to disperse and degrade. Based on its high molecular weight, the notified polymer is not expected to be bioaccumulative. A minor amount of notified polymer, as residues in empty containers, is expected to be disposed of to landfill or recycling facilities. The notified polymer is expected to degrade through biotic and abiotic processes to form water, oxides of carbon and phosphorus and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) can be estimated as outlined below. The calculations are based on the worst case assumptions of complete discharge of the total annual import of the notified polymer to receiving waters via sewage treatment plants (STPs) nationwide. It was assumed none of the notified polymer would be removed from STP effluents.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	100,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	100,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	273.97	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	64.74	µg/L
PEC - Ocean:	6.47	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 64.7 µg/L may potentially result in a soil concentration of approximately 0.432 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 2.16 mg/kg and

4.32 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicological data for the notified polymer were submitted. 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 applies to the notified polymer. The algal toxicity median effective concentrations (EC50) for this type of polymer are reported to be in the range of 1 – 10 mg/L (Boethling & Nahbolz, 1997). However, the indirect toxicity to algae is likely to be mitigated due to the presence of calcium ions present in sewage treatment plant (STP) effluent and in surface waters, which can bind to the functional groups of the notified polymer. The mitigation factor (i.e. decrease in toxicity to algae) arising from the binding of calcium ions has been demonstrated to be > 10 (Boethling & Nahbolz, 1997).

The notified polymer may pose a hazard to algae by indirect toxicity. Whilst use of representative analogue data is considered reliable to provide general indications of the likely environmental effects of the polymer, the data is not considered adequate to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was calculated assuming a lower limit of toxicity for the notified polymer, from the toxicity range (EC50 = 1-10 mg/L) which is characteristic of the class of polymers to which it belongs. An assessment factor of 100 was used as algae is known to be the most sensitive taxa (out of the three standard trophic levels, i.e. fish, invertebrates and algae) to this class of chemicals. The PNEC was mitigated by a conservative factor of 10 to take into account the expected binding of the notified polymer by calcium ions in receiving waters with typical water hardness.

EC50 (algae, 96 h)	> 1	mg/L
Assessment Factor	100	
Mitigation factor	10	
PNEC (mitigated)	> 100	µg/L

7.3 Environmental Effects Assessment

The risk quotients ($Q = PEC/PNEC$) are calculated below:

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC (mitigated) µg/L</i>	<i>Q</i>
Q - River:	64.74	> 100	< 0.647
Q - Ocean:	6.47	> 100	< 0.0647

The above risk quotients are upper limits as they have been calculated using a conservative algal toxicity and mitigation factor. The notified polymer is likely to reach surface waters, however toxicity is expected to be mitigated by prevailing water hardness. The notified polymer is not expected to be bioaccumulative. As the risk quotient is < 1 for the worst case effluent discharge scenario, the notified polymer is not expected to pose an unreasonable risk to the environment on the basis of its assessed use pattern and maximum annual importation volume.

8. RISK ASSESSMENT (Extension Application)

While the introduction volume will increase, the proposed use of the notified polymer will not change significantly under the proposed extension. Therefore, the circumstances in the extension application are not expected to impact on the original human health and environmental risk assessment and recommendations.

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