

File No PLC/713

September 2007

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

FULL PUBLIC REPORT

Lewatit MonoPlus TP 207

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 and Water Resources.

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, 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**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL.....	3
3. PLC CRITERIA JUSTIFICATION	3
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH IMPLICATIONS	5
6.1. Exposure Assessment.....	5
6.2. Toxicological Hazard Characterisation.....	5
6.3. Human Health Risk Assessment.....	6
7. ENVIRONMENTAL IMPLICATIONS.....	6
7.1. Exposure Assessment.....	6
7.2. Environmental Hazard Characterisation	6
7.3. Environmental Risk Assessment	6
8. CONCLUSIONS	7
8.1. Level of Concern for Occupational Health and Safety.....	7
8.2. Level of Concern for Public Health	7
8.3. Level of Concern for the Environment.....	7
9. MATERIAL SAFETY DATA SHEET	7
9.1. Material Safety Data Sheet.....	7
10. RECOMMENDATIONS.....	7
10.1. Secondary Notification	7

FULL PUBLIC REPORT**Lewatit MonoPlus TP 207****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Lanxess Pty Ltd (ABN: 58 071 919 116) of Unit 1, 31 Hill Road, Homebush Bay NSW 2127

NOTIFICATION CATEGORY

Polymer of Low Concern

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, Reactive Functional Groups, Purity, Manufacture/Import Volume, and Site of Manufacture/Reformulation

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

EIP issued during assessment

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Lewatit MonoPlus TP 207

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) $>10^6$ Da

REACTIVE FUNCTIONAL GROUPS

The notified chemical contains high concern functional groups. However, as an ion-exchange resin, it will only be imported in a solid form, and will be used only in a solid form; it is not soluble or dispersible in water, and it will not be released to sewer or the aquatic environment.

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.

eventually it loses efficiency and can then be disposed of to landfill or incinerated. The resin is expected to be replaced over a five to ten year period, as it loses effectiveness.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

<i>Category of Workers</i>	<i>Number</i>	<i>Exposure Duration</i>	<i>Exposure Frequency</i>
Transport and storage workers	4	2-3 hours/day	4 days/year
Ion exchange resin handlers	10-15	3 hours/day	20 days/year

Transport and storage

There is little potential for occupational exposure to the notified polymer during transport and storage of the imported product.

Ion Exchange Resin Column Handlers

During loading of the ion exchange resin to tanks, skin and eye exposure to the notified polymer may occur at various stages of the process. For example, exposure may occur during manual tipping of the polymer, column packing (loading and recharging) cleaning up of spills and during maintenance. However, as the notified polymer beads are damp there is negligible potential for dust generation. Accidental exposure to the eye may cause mechanical injury.

Where exposure to the notified polymer may occur, during loading or emptying, personal protective equipment, such as safety glasses, impervious gloves and coveralls, will be provided. During use, the resin beads containing the notified polymer are in sealed equipment operated automatically and the potential for incidental exposure to operating personnel is negligible.

Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is limited because of the automated processes, and the engineering controls and personal protective equipment worn by workers.

PUBLIC EXPOSURE

The notified polymer is intended only for use in industry and as such public exposure to the notified chemical is not expected.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer or on an analogous chemical.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral	LD50 >5000 mg/kg bw	No	No	Other
Rabbit, skin irritation	Non-irritating	No	Unknown*	Unknown*
Rabbit, eye irritation	Non-irritating	No	Unknown*	Unknown*

All results were indicative of low hazard. "Unknown" data, above (marked with an asterisk, "*"), is sourced from the MSDS for the imported product conducted on an unknown analogous chemical. Test reports were not available.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

The OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the fact that the polymer meets the PLC criteria. Workers will use appropriate engineering controls and PPE to prevent exposure to the notified polymer. Respirable sized (< 10 µm) dust of water insoluble, high molecular weight polymers (> 10000 Da) have the potential to cause lung overloading. There is no information on the inhalation toxicity of the polymer. However, as the notified polymer is introduced in a form that will not be able to cause inhalation exposure, and given that worker exposure is generally limited, the risk to occupational health and safety is considered to be acceptable.

PUBLIC HEALTH

As there will be no exposure of the public to the notified polymer, the risk to the public from exposure to the notified polymer is considered to be negligible.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer will not be manufactured or reformulated in Australia.

The imported product is in the form of beads. In the event of an accidental leakage, clean-up procedures (containment and manual collection) are expected to efficiently remove the majority of the released notified polymer. Annually, it is estimated that 1% will be lost due to spills during transport, handling and filling of filter columns, i.e. <10,000 kg. Any spilt material will be collected and placed in sealed containers ready for disposal to landfill. Empty import bags will also be disposed of to landfill, and it is estimated that 0.2% may remain as residue in bags i.e. <2000 kg.

The notified polymer is an ion exchange resin that will be used in filter columns to extract heavy metal cations in the mining industry. The filter columns are not cleaned between emptying and refilling with resin, so no waste-cleaning stream is created. The spent polymer resin will be drummed and disposed of to landfill.

ENVIRONMENTAL FATE

The majority of the imported resin beads of the notified polymer once spent will end up in landfill on the mine sites where it is used. Here, it is expected to remain immobile within soil. The notified polymer is not expected to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted.

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 highest toxicity is when the acid groups are on alternating carbons of the polymer backbone. This does not apply to the notified polymer. Any potential for toxicity to algae is likely to be further reduced due to the presence of calcium ions in the aqueous environment, which will bind to the functional groups. Further, resins of this type are accepted as PLCs, as the aquatic exposure is likely to be very low. The notifier stated that the notified polymer would not be released to sewer or natural waterways.

7.3. Environmental Risk Assessment

The notified polymer resin will be used on mining sites. The ultimate fate of the resin is to be buried in landfill on the mine site, where it is expected to remain immobile within soil and eventually will degrade through biotic and abiotic processes.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is low risk to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is negligible concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

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

9. MATERIAL SAFETY DATA SHEET

9.1. 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.

10. 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

- Avoid dispersal of spilled material, run-off, and contact with soil, waterways, drains and sewers. During the handling of spills, move containers from the spilled area. Prevent entry of the material into sewers, watercourses, basements or confined areas.
- Vacuum or sweep up material and place in a designated labelled waste container. Dispose of via a licensed waste disposal contractor.

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 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.
 - significant changes in operational description occur, e.g., the notified polymer is likely to enter the sewer or natural waterways.
 - any proportion of particle size distribution is $< 10 \mu\text{m}$.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from an ion-exchange resin, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 1000 tonnes, 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.