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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Lewatit TP 260

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

TABLE OF CONTENTS

FULL PUBLIC REPORT

Lewatit TP 260

1. APPLICANT AND NOTIFICATION DETAILS

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

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, Other names, Molecular and structural formulae, CAS Number, Means of identification, Molecular weight, Polymer constituents, Residual monomers and impurities, Reactive functional groups, Import volume and Purity.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Physical and chemical properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Not known

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Lewatit TP 260
Lewatit Monoplus TP 260

MOLECULAR WEIGHT
NAMW > 10,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None expected during use.

DEGRADATION PRODUCTS
The notified polymer is not designed nor expected to degrade, decompose, or depolymerize.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Beige opaque solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Due to its cross-linked nature the notified polymer would be expected to decompose before melting.
Boiling Point	Not determined	The notified polymer is a solid.
Density	Approximately 1200 kg/m^3	MSDS
Bulk Density	730 to 810 kg/m^3 at 20°C	MSDS
Vapour Pressure	Not determined	The notified polymer is heavily cross-linked and has very high molecular weight and is not expected to have any significant vapour pressure
Water Solubility	Not Determined	The notified polymer is heavily cross-linked and has very high molecular weight and is not expected to have any significant solubility in water
Hydrolysis as a Function of pH	Not Determined	The notified polymer is heavily cross-linked and has very high molecular weight and is not expected to have any significant solubility in water. There are no hydrolysable groups.
Partition Coefficient (n-octanol/water)	Not Determined	The notified polymer is heavily cross-linked and has very high molecular weight and is not expected to have any significant solubility in water. However, solubility in octanol may also be low.
Adsorption/Desorption	Not Determined	The notified polymer is heavily cross-linked and has very high molecular weight and is not expected to have any significant solubility in water. Therefore the notified polymer is expected to associate with soils/sediments.
Dissociation Constant	Not Determined	The notified polymer is anionic and will remain so in environmental pH range of 4-9.
Particle Size	Not Determined	The notified polymer will be imported as resin beads with diameters ranging from 0.4 to 1.25 mm.
Flash Point	Not Determined	The notified polymer is a solid and due to its cross-linked nature and high molecular weight the notified polymer is not expected to have any significant vapour pressure and therefore the flash point is expected to be high.
Flammability	Not Determined	Due to its cross-linked nature and high molecular weight the notified polymer is expected to have limited flammability.
Autoignition Temperature	Not Determined	The notified polymer is not expected to autoignite under normal conditions of use.
Explosive Properties	Not Determined	The notified polymer is not expected to be explosive based on the absence of structural alerts.

DISCUSSION OF PROPERTIES

The notified polymer will be introduced into Australia in the form of resin beads with diameters ranging from 0.4 to 1.25 mm. The amount of inhalable (< 100 μm) and respirable (< 10 μm) particles in the notified polymer as introduced is therefore likely to be very low.

Reactivity

The notified polymer is an ion exchange resin and can undergo H+ and metal cation exchange reactions. Otherwise, the polymer beads are chemically stable under normal use conditions.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be imported and supplied to end users as polymer beads with a diameter ranging from between 0.4 and 1.25 mm.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	300-1,000	300-1,000	300-1,000	300-1,000	300-1,000

PORT OF ENTRY
Sydney, Devonport and Melbourne.

IDENTITY OF MANUFACTURER/RECIPIENTS
Lanxess Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be packed in 1,000 L bulker bags, 200 L lined fibre drums or 25 L plastic bags shrink-wrapped onto 1,000 L pallets. The notified polymer will be transported from the wharf to a warehouse and stored until required for dispatch to end users. The notified polymer will remain in its original packaging until it reaches the customer site.

USE
Ion exchange resin used for processing waste streams from industrial process or for purification of brine.
The notified polymer resin will be used in treatment plants for the selective extraction of metal cations.

OPERATION DESCRIPTION
The notified polymer will not be manufactured or reformulated in Australia. It will be imported and supplied to customers as polymer beads (particle diameter ranging between 0.4 and 1.25 mm).

Transport and storage
The notified polymer resin will be stored under cover until required. When required, the sealed bulker bags, 200 L lined fibre drums and/or 25 L plastic bags are moved by forklifts to the process unit.

End use
The notified polymer resin beads are manually poured into a holding tank where they are treated with a solution of 5% mineral acid to condition the resin for use. It will then be mixed with a thickened slurry of ground ore which has been previously treated with acid (and possibly an activated solvent depending on the processing path) to form a metal salt.

The mixing of the notified polymer resin with the slurry occurs within a series of large stirred tanks of volume in excess of 50,000 litres and the resin absorbs the required metal from the salt. The notified polymer resin is then separated from the ore by passing the mixture over screens, the mesh size of which is larger than the ore particles but smaller than the resin.

The collected resin is then transferred to large columns of capacity between 10 cubic metres and 100 cubic metres where the resin is treated with mineral acid to recover the metal and prepare the resin for re-use. The resin can be re-used until eventually it loses efficiency and can then be disposed of to land fill or incinerated. The column packing resin would be replaced over a five to ten year period, as the resin loses effectiveness.

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)*
Transport and storage workers	4	2-3	4
Ion exchange resin handlers	10-15	3	20

EXPOSURE DETAILS

Transport and storage

It is anticipated that waterside, transport and warehouse workers would only be exposed to the notified polymer in the event of an accidental spill. Should a spill occur, it is expected to be contained and collected into suitable containers for recovery or disposal in accord with the MSDS and official regulations.

End use

During loading of the ion exchange resin to tanks, dermal and ocular exposure to the notified polymer may occur during manual tipping of the polymer, column packing (loading and recharging) cleaning up of spills and during maintenance. Accidental exposure of the notified polymer 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, is provided. As the notified polymer beads are damp the potential for dust generation is low and therefore the potential for inhalation exposure is minimal. 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.

6.1.2. Public exposure

Public exposure to the notified polymer is expected to be negligible. The notified polymer will be imported, warehoused and then transported to commercial customers only. Exposure to the public will only occur in the event of spill or industrial accident during the transport and storage of the notified polymer.

6.2. Human health effects assessment

The results from toxicological investigations conducted on an analogue are summarised in the table below. Details of these studies can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 3000 mg/kg bw low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating

Toxicokinetics

Based on its very high molecular weight and crosslinking the notified polymer is not expected to be readily absorbed transdermally or from the gastrointestinal tract.

General toxicity

The notified polymer is considered to be of low acute toxicity via the oral route based on a test conducted with an analogue polymer in rats. This correlates with the notified polymers predicted lack of gastrointestinal absorption. The possible acute effects of inhalation of respirable particles of the notified polymer are not known.

Inhalation of respirable or inhalable particles of the notified polymer may pose a potential health hazard with respirable particles of greater concern than inhalable particles. Inhaled particulates are known to interfere with cell function in the airways, causing inflammatory-like reactions [R.C. Rylander (1997)]. Therefore, bronchial or pulmonary irritation is possible following inhalation exposure to particles containing the notified polymer, arising from deposition of water-insoluble particles in the lung. The US EPA have similarly expressed concern regarding high molecular weight (70,000 Da or greater) insoluble polymer particles of respirable size, as they can potentially result in irreversible lung damage.

The functional groups present in the notified polymer also suggest that it may also be water absorbing. Water absorbing polymer particles of respirable size are a potential health concern, because of data from a 2-year

chronic inhalation study for a water-absorbing polyacrylate polymer, where lung tumours were observed in rats following exposure to 0.2-0.8 mg/m^3. Based on this, and in the absence of relevant toxicological data the introduction of respirable particles of the notified polymer may present a significant risk to human health.

Irritation and Sensitisation.
Based on tests conducted on an analogue polymer in rabbits the notified chemical is considered to be non-irritating to the skin.
In an eye irritation test conducted in rabbits, the analogue polymer was found to cause moderate to severe conjunctival irritation as well as mild corneal opacity and iridal inflammation. The notified polymer is therefore considered to be irritating to the eye.

Health hazard classification
Based on the eye irritation test on a close analogue the notified polymer is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Xi: R36 Irritating to eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The main route of exposure to the notified polymer for workers is expected to be dermal exposure, during processes such as manual tipping of the polymer, column packing (loading and recharging) cleaning up of spills and during maintenance. The notified polymer is not expected to be absorbed transdermally and was non-irritating to the skin and hence the risk to workers from dermal exposure is considered to be low.
The notified polymer will be imported in the form of beads that will be damp when handled. Although a closely related analogue was shown to be an eye irritant the low potential for ocular exposure ensures that the risk of the notified chemical causing eye irritation in workers is considered to be low. In addition the workers are expected to be wearing PPE, which would further minimise the risk.

While the notified polymer was found to be of low acute toxicity via the oral route, health effects after repeated exposure are unknown, although the unfavourable physical-chemical properties for dermal and gastrointestinal absorption make adverse effects unlikely.

Although the notified polymer may present a significant risk to human health if inhaled as respirable particles, it will only be introduced as polymer beads (particle diameter ranging between 0.4 and 1.25 mm). Therefore the risk to workers would not be considered unacceptable.

6.3.2. Public health
As the public are not expected to be exposed to the notified polymer, the risk to public health is considered to be negligible.

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 or reformulated in Australia. It will be warehoused and sent to customer site as required for end use.

RELEASE OF CHEMICAL FROM USE
Since the imported notified polymer will be 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% (i.e. <1000 kg) is expected to be lost due to spills during transport, handling and filling of filter columns. Any spilt material will be collected and placed in sealed containers ready for disposal to landfill.

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.

Empty import bags/drums will be disposed to landfill. It is estimated that 0.2% may remain as residue in bags i.e. < 200 kg.

The spent polymer resin from filter columns will be drummed and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL
Disposal of spent resin will be to landfill.

7.1.2 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 and eventually degrade to landfill gases including oxides of carbon, and nitrogen, salts of metals/non-metals and water vapour.

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 effects assessment

No ecotoxicity 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 is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups.

7.2.1 Predicted No-Effect Concentration
As direct release to the aquatic environment is not expected, it is not possible to calculate a PEC.

7.3. Environmental risk assessment
The notified polymer resin will be used on mining and industrial sites. The ultimate fate of the resin is to be buried in landfill, where it is expected to remain immobile within soil. The potential environmental hazard is low if the notified polymer is used in the typical manner outlined.

Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

Xi: R36 Irritating to eyes

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Eye irritation	Category 2A	Causes serious eye irritation

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

REGULATORY CONTROLS
Hazard Classification and Labelling

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - Conc ≥ 20%: R36

- The following safety phrases should appear on the MSDS and label for the product containing the notified polymer:
  - S25: Avoid contact with eyes
  - S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to powders containing the notified polymer during handling:
  - Local exhaust ventilation and adequate general ventilation should be applied at sites if respirable particles are handled.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid eye contact
  - Workers must have adequate education and training before handling the notified chemical.
  - Avoid the formation of airborne dusts.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer.
  - Safety glasses
  - dust mask (adequate for respirable particle sizes, if they are present).

  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.

Storage

- Keep in a cool dry place. Avoid temperature above 40°C and below -20°C.

Emergency procedures

- Avoid dispersal of spilled material, run-off, and contact with 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.

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 an ion exchange resin, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1,000 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.

Material Safety Data Sheet
The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue
METHOD	EC Directive 84/449/EEC Acute Toxicity (Oral).
Species/Strain	Rat/SPF-bred Wistar Bor: WISW (SPF Cpb)
Vehicle	The test substance was suspended in tap water and administered by gavage.
Remarks - Method	Due to the high viscosity a single dose of 3000 mg/kg was not possible and two equal doses of 1500 mg/kg were used instead, separated by a 7 h time period.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	3000	0

LD50	> 3000 mg/kg bw
Signs of Toxicity	There were no test substance-related clinical signs.
Effects in Organs	A reddening of the mucosa of the glandula stomach was established in 3 female rats.
Remarks - Results	There were no deaths. All animals showed normal body weight gain throughout the study.
CONCLUSION	The test substance is of low toxicity via the oral route.
TEST FACILITY	Bayer AG (1987a)

A.2. Irritation – skin

TEST SUBSTANCE	Analogue
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 male
Vehicle	The test substance was made into a paste with water.
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations.
Remarks - Results	The test substance did not produce erythema or oedema in any of the test subjects.
CONCLUSION	The test substance is non-irritating to the skin.
TEST FACILITY	Bayer AG (1987b)

A.3. Irritation – eye

TEST SUBSTANCE Analogue

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit/New Zealand White
Number of Animals 3 male
Observation Period 14 days
Remarks - Method No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2.7	3	2.7	3	< 14 days	0
Conjunctiva: chemosis	2.3	2.3	2	3	< 14 days	0
Conjunctiva: discharge	1	1	0.6	3	< 48 hours	0
Corneal opacity	1	1	1	1	< 14 days	0
Iridial inflammation	0.3	0.3	0.3	1	< 48 hours	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results All three animals showed diffuse, beefy red-coloured conjunctiva at the 24 and 48-hour observations and reddening up to at least 7 days after administration. Severe conjunctival swelling was observed in all animals up to 7 days after exposure to the test substance.
Other observations include retention of fluorescein dye in the conjunctival membranes for 7 days after exposure to the test substance.

CONCLUSION The test substance is irritating to the eye.

TEST FACILITY Bayer AG (1987b)

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