

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Retingan ZF Plus

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of the Environment.

This Public Report is 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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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
PLC/1353	Lanxess Pty Ltd	Polymer in Retingan ZF Plus	No	≤ 8 tonnes per annum	Component of leather retanning products

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment

On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment, provided that the notified polymer released to sewer from any site of use does not exceed 8.20 µg/L.

Health and Safety Recommendations

- 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 (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Environmental Recommendations

- The following concentration limits should be implemented by all users for release of the notified polymer to the environment:
 - The concentration of the notified polymer released to sewer from any site of use should not exceed 8.20 µg/L.
 - The notified polymer is not to be released directly to surface waters.
- The following control measures should be implemented by all users to minimise environmental exposure during use of the notified polymer:
 - Notified polymer, or waste water containing the notified polymer are to undergo sewage treatment processes such that the concentration of the notified polymer in effluent is < 8.20 µg/L.

- The following monitoring should be conducted by all users to measure environmental release during use of the notified polymer:
 - Effluent released from any site of use should be analysed by a reliable and validated method to ensure that the concentration of the notified polymer in effluent is < 8.20 µg/L.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

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 polymer 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 polymer, 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of leather retanning products, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the notified 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 (M)SDS of a product containing the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Lanxess Pty Ltd (ABN: 58 071 919 116)
Unit 1, 31 Hill Road
HOMEBUSH BAY NSW 2150

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, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

Retingan ZF Plus (product containing the notified polymer at < 25%)

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 Da.

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.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	The powder mixture that the polymer will be introduced in is a yellow solid.
Melting Point/Glass Transition Temp	Not determined. Decomposition is expected to occur at high temperature, prior to melting.
Density	500 kg/m ³ at 20 °C (bulk density)
Water Solubility	> 0.125 g/L
Dissociation Constant	pKa = 0.2 ± 0.9 (acid) pKa = 5.1 ± 0.4 (base)
Particle Size	Not determined. The powder is moderately hygroscopic and it is unlikely to form fine dust (information provided by the notifier).
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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	4-8	4-8	4-8	4-8	4-8

Use

The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia as a component of a mixture in powder form (at < 25% concentration), transferred to retanning area, weighted out manually and transferred to a retanning drum where an aqueous solution containing the notified polymer at 1-2% concentration is made depending on the thickness of leather. After the two-step retanning process, the leather will be dyed and fatliquored to form end products (treated leather). Leather retanned with Retingan ZT Plus containing the notified polymer is exported and used primarily in high cost finished leather items such as football boots.

6. HUMAN HEALTH RISK ASSESSMENT

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

Occupational Health and Safety Risk Assessment

Inhalation exposure to the introduced product (containing < 25% notified polymer) in powder form is possible. The notified polymer is water soluble (> 0.125 g/L) and if inhaled should be cleared from the respiratory tract. The expected use of a closed mixing system, dust masks and local exhaust ventilation when handling the powdered notified polymer by reformulation workers should reduce inhalation exposure levels and hence lower the risk of temporary lung overloading. Therefore, given the assumed low hazard and use pattern, the risk to workers is not considered unreasonable.

Public Health Risk Assessment

The notified polymer will not be sold to the public. There is potential for dermal exposure by the public to leather that contains the notified polymer. However, once processed and dried, the notified polymer will be bound to the collagen fibre and not available for exposure. Therefore, the risk to public health is not considered unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

Anionic polymers are generally of low toxicity to fish and daphnia, however they are known to be 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 supported by results from ecotoxicological investigations conducted on the notified polymer, which are summarised in the table below. The actual concentrations of the notified polymer in the test media were determined at the conclusion of each study. The results of these studies are considered reliable as the validity criteria for all of the tests were satisfied.

Endpoint	Results	Assessment Conclusion	Reference
Fish Toxicity <i>Danio rerio</i>	96 h LC50 > 100 mg/L	Not harmful to fish	Currenta (2008a)
Aquatic Invertebrate Toxicity <i>Daphnia magna</i>	48 h EC50 > 100 mg/L	Not harmful to <i>Daphnia</i>	Currenta (2008b)
Algal Toxicity <i>Desmodesmus subspicatus</i>	72 h E _r C50 = 21.65 mg/L 72 h E _r C10 = 0.41 mg/L	Harmful to algae Very toxic to algae with long lasting effects	Currenta (2008c)

Based on the above ecotoxicological endpoints for the notified polymer, it is expected to be harmful to algae on an acute basis, but is not expected to be harmful to fish or aquatic invertebrates. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as “Acute Category 3; Harmful to aquatic life”. Based on the above ecotoxicological endpoints and its lacking of ready biodegradability, the notified polymer is expected to be very toxic to algae on a chronic basis. Therefore, the notified polymer is formally classified as “Chronic Category 1; Very toxic to aquatic life with long lasting effects” under the GHS.

The notified polymer will be imported as a finished product and used as a component of aqueous dispersions, which will be applied to leather by immersion. No reformulation or repackaging will occur in Australia. The notified polymer is expected to be exhausted onto the leather substrates at > 89%. The remaining 11% of the notified polymer in the treatment solution will be discharged to an onsite waste water treatment plant for treatment before release to surface waters. Release of the notified polymer to the environment during import, storage, and transport is expected to be limited to accidental spills or leaks. Spills or accidental release of the product containing the notified polymer are expected to be collected with adsorbents and disposed of to landfill in accordance with local government regulations.

Based on the results of an inherent biodegradability study conducted in accordance with OECD TG 302 B guidelines (Currenta, 2008d), the notified polymer is not considered readily or inherently biodegradable (10% in 28 days). However, based on its high molecular weight the notified polymer in surface waters is not expected to cross biological membranes, and is therefore unlikely to be bioaccumulative.

Based on the notifier’s estimate, it is expected that the majority of the notified polymer will be exhausted onto the leather substrates, with up to 11% released to an onsite effluent treatment system. During waste water treatment, residual notified polymer will be removed by adsorption to sludge. Up to 50% of the notified polymer is expected to adsorb to sludge and sediment during sewage treatment plant (STP) processes, based on its high molecular weight and anionic properties (Boethling and Nabholz, 1997), with sludge eventually disposed of to landfill or re-used for soil remediation. The predicted environmental concentration (PEC) has been calculated based on application and release of the notified polymer at a single site producing 80 ML of effluent daily (stated by the notifier), across 260 working days per annum.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	8,000	kg/year
Proportion expected to be released to sewer	11%	
Annual quantity of chemical released to sewer	880	kg/year
Days per year where release occurs	260	days/year
Daily chemical release	3.38	kg/day
Individual sewage treatment plant average daily effluent production	80	ML
Removal within STP	50%	mitigation
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River	21.154	µg/L
PEC – Ocean	2.115	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 211.54 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1,500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified polymer may be approximately 1.41 mg/kg in applied soil. This assumes that degradation of the notified polymer occurs in the soil within 1 year from application. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated biosolids application,

the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 7.05 mg/kg and 14.10 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 21.15 µg/L may potentially result in a soil concentration of approximately 141.0 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately 705.1 µg/kg and 1,410 µg/kg, respectively.

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 50 was used given acute endpoints for three trophic levels and one chronic endpoint are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E _r C10 (Algae, 72 h)	0.41	mg/L
Assessment Factor	50	
PNEC:	8.20	µg/L

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) has been calculated based on the above PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	21.154	8.20	2.580
Q – Ocean	2.115	8.20	0.258

The Risk Quotient ($\text{RQ} = \text{PEC}/\text{PNEC}$) for river exposure was calculated to be $\text{RQ} > 1$, based on the above calculated PEC and PNEC values. For the $\text{PEC} < \text{PNEC}$, and therefore the Risk Quotient for river exposure to be $\text{RQ} < 1$, all measures should be taken to ensure $\leq 4.25\%$ release of the notified polymer to an onsite effluent treatment system at a single site of application.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	8,000	kg/year
Proportion expected to be released to sewer	4.25%	
Annual quantity of chemical released to sewer	340	kg/year
Days per year where release occurs	260	days/year
Daily chemical release	1.308	kg/day
Individual sewage treatment plant average daily effluent production	80	ML
Removal within STP	50%	mitigation
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River	8.173	µg/L
PEC – Ocean	0.817	µg/L

The Risk Quotient ($Q = \text{PEC}/\text{PNEC}$) based on the calculated PEC at 4.25% release to a single STP is summarised in the table below.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	8.173	8.20	0.997
Q – Ocean	0.817	8.20	0.100

The notified polymer is not readily biodegradable. Based on its high molecular weight the notified polymer is not expected to be bioaccumulative. In landfill and in surface waters, the notified polymer is expected to eventually disperse and degrade by biotic and abiotic processes to form water and

oxides of carbon, sulphur and nitrogen. To ensure the notified polymer does not pose an unreasonable risk to the environment, all measures should be taken to ensure the notified polymer released to sewer from any site of use does not exceed 8.20 µg/L.

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