

File No: LTD/1729

April 2014

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

PUBLIC REPORT

Polymer in Additin[®] RC 8100

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

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:

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**Director
NICNAS**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS.....	5
1. APPLICANT AND NOTIFICATION DETAILS.....	5
2. IDENTITY OF CHEMICAL.....	5
3. COMPOSITION	5
4. PHYSICAL AND CHEMICAL PROPERTIES	5
5. INTRODUCTION AND USE INFORMATION.....	6
6. HUMAN HEALTH IMPLICATIONS	7
6.1. Exposure Assessment.....	7
6.1.1. Occupational Exposure.....	7
6.1.2. Public Exposure.....	8
6.2. Human Health Effects Assessment	8
6.3. Human Health Risk Characterisation	8
6.3.1. Occupational Health and Safety.....	8
6.3.2. Public Health.....	9
7. ENVIRONMENTAL IMPLICATIONS.....	9
7.1. Environmental Exposure & Fate Assessment	9
7.1.1. Environmental Exposure.....	9
7.1.2. Environmental Fate	9
7.1.3. Predicted Environmental Concentration (PEC).....	10
7.2. Environmental Effects Assessment.....	10
7.2.1. Predicted No-Effect Concentration.....	10
7.3. Environmental Risk Assessment.....	10
<u>APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS</u>	11
C.1. Environmental Fate.....	11
C.1.1. Ready biodegradability	11
BIBLIOGRAPHY	12

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1729	Lanxess Pty Ltd	Polymer in Additin® RC 8100	ND*	≤ 50 tonne/s per annum	A component of lubricant oils

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

Provided that the recommended occupational health and safety controls are being adhered to, under the conditions of the occupational setting, 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 assessed use pattern and low potential for aquatic exposure, the notified polymer is not expected to pose an unreasonable risk to the environment when it is used as proposed.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer:
 - Enclosed, automated processes, where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid contact with skin and eyes
 - Clean up spills promptly
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Impervious gloves
 - Eye protection
 - Protective clothing

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 for the 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.

Disposal

- The notified polymer should be disposed of to landfill in accordance with local regulations for recycling, re-use or recovery.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical collection and subsequent safe disposal.

Transport and Packaging

The notified polymer is not classified as Dangerous Goods.

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 1,000;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of lubricant oils, or is likely to change significantly;
 - the amount of polymer being introduced has increased, 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 (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Lanxess Pty Ltd (ABN: 58 071 919 116)
Unit 1/31 Hill Road
Sydney Olympic Park NSW 2127

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ 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, degree of purity, polymer constituents, residual monomers, impurities, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Additin® RC 8100

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 90%

DEGRADATION PRODUCTS

None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Viscous, white to yellowish liquid.

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Liquid at room temperature
Boiling Point	Not determined	Decomposition is expected to occur prior to boiling point being reached
Density	1,000 kg/m ³ at 20 °C	(M)SDS
Vapour Pressure	$< 1.3 \times 10^{-9}$ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	Not determined	Expected to be low due to the predominantly hydrophobic structure and the high molecular weight of the notified polymer.
Hydrolysis as a Function of pH	Not determined	The notified chemical contains hydrolysable functionality. However, significant hydrolysis is not expected at environmental pH (4–9).
Partition Coefficient	Not determined	The notified polymer is expected to partition

(n-octanol/water)		from water to n-octanol on the basis of its low water solubility
Adsorption/Desorption	Not determined	Based on its expected low solubility in water, the notified polymer is expected to adsorb strongly to soil, sediment and sludge.
Dissociation Constant	Not determined	No dissociable functionality.
Flash Point	> 250 °C at 101 kPa	(M)SDS
Flammability	Not determined	Not expected to be flammable based on the high flash point.
Autoignition Temperature	Not determined	Not expected to undergo auto-ignition under normal conditions of use.
Explosive Properties	Not determined	Not expected to have explosive properties based on lack of structural alerts
Oxidising Properties	Not determined	Not expected to have oxidising properties based on lack of structural alerts

Reactivity

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

Physical hazard classification

Based on the submitted physicochemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported in neat form for local reformulation or it may be imported as a component of various types of hydrocarbon oils at concentrations between 5 and 80%.

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

Year	1	2	3	4	5
Tonnes	1–10	10–20	20–30	30–40	40–50

PORT OF ENTRY

Sydney and Melbourne

TRANSPORTATION AND PACKAGING

The notified polymer will be imported and stored in 205 L drums. End use products will be stored in various types of containers.

USE

The notified polymer is a multifunctional lubricant additive for use in metal working and metal forming fluids, and as a thickener in hydraulic fluids for turbine and gear oils, at concentrations up to 80%. When added to the fluids the notified polymer is proposed to enhance extreme pressure, anti-wear and lubricity properties. When the lubricants containing the notified polymer are applied to metal surfaces, a thermally stable and persistent film is formed. Such end use lubricant products are only intended for industrial applications.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia. The notified polymer will be imported in neat form and will be reformulated locally.

Reformulation

During reformulation, the imported neat notified polymer will be transferred from the imported containers into a blending tank using automated pumping/dosing equipment. The containers will be opened by workers and connected to the blend vessels by pipes/hoses using quick connect fittings. The blending vessel will be sealed and supplied with local fume extraction. The blending vessel will also be located in a bunded area to capture any spills. Quality assurance staff may take samples for analysis from a sampling port on the blending vessel. Once

blending has been completed, the finished product will be gravity fed to an automated filling machine where the product will be filled into various types of end-use containers.

End use

Oil based metal working fluids containing the notified polymer will be used in metal forming mill and lathe unit operations. The metal working fluids are expected to be manually transferred into the equipment. These operations are expected to be conducted within enclosed machinery with the metal surface being coated with excess fluid dripping down into a sump. The notifier states that local exhaust ventilation is expected to be in place. Hydraulic fluids will be pumped into a range of machinery at equipment manufacturer sites. Gear oils containing the notified polymer will be transferred manually (when used in small volumes, < 4 L) or pumped into industrial machinery (from 205 L drums).

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>
Transport and warehousing	4	30
Blending plant operators	5	12
Blending quality assurance (QA) staff	2	12
End-use plant operators	4–12	200

EXPOSURE DETAILS

Transport and storage

Transport workers and warehouse workers would only be exposed to the notified polymer in the event of an accident. The transfer facilities are expected to be well-ventilated with control systems for accidental spills, minimising the risk of worker exposure to the notified polymer during these stages.

Reformulation

Dermal and ocular exposure to the notified polymer (up to 100% concentration) is possible when blending plant operators are connecting and disconnecting pump lines to storage tanks or blending vessels. The blending process employs a fully automatic and enclosed system; exposure to workers is not expected. Dermal exposure (up to 100% concentration) is possible when cleaning up spills or leaks and during maintenance of the blending equipment. The notifier states that workers involved in the blending process are expected to wear gloves, eye protection and protective clothing to minimise exposure to the notified polymer.

Transfer of the finished lubricant containing the notified polymer at ≤100 % concentration to packaging will be performed using automated processes; exposure to workers is not expected. Inhalation exposure is expected to be negligible given the predicted very low vapour pressure of the notified polymer (3.36×10^{-43} kPa at 25 °C), unless aerosols or mists are generated. In addition, the notifier states that blending and packaging facilities are expected to be well ventilated and appropriate engineering controls in place.

Sampling

At reformulation facilities samples will be taken from blending vessels for quality assurance testing. Dermal exposure to the notified polymer (up to 100% concentration) may occur during sampling. To minimise exposure, the notifier states that QA staff are expected to wear gloves, eye protection and long sleeved lab coats.

End use

There is potential for dermal and ocular exposure to the notified polymer at concentrations up to 80% by plant operators and maintenance workers may occur during the charging, topping up and maintenance activities of the industrial machinery and equipment. The notifier states that exposure will be minimised by the use of gloves, goggles and protective clothing.

There is potential for dermal, ocular and inhalation exposure to the notified polymer by plant operators use the notified polymer in metal working fluids. The notifier states that inhalation exposure will be minimised by the use of enclosed processes and local exhaust ventilation in addition to PPE.

6.1.2. Public Exposure

The notified polymer and the products containing it are expected to be used in industrial settings only. Therefore, given the proposed use pattern, public exposure is not expected except in the event of accidental release.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

However, the supplied MSDS for the notified polymer summarises results from toxicological investigations conducted on an unidentified analogue of the notified polymer. These results are summarised in the following table.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2,000 mg/kg bw; Analogue was found to be of low oral toxicity
Skin irritation	Analogue was found to be non-irritating
Eye irritation	Analogue was found to be non-irritating

Toxicokinetics, metabolism and distribution.

Based on the use patterns provided, the main routes of exposure for the notified polymer are expected to be dermal and ocular. The notified polymer is not expected to be absorbed across biological membranes to a significant extent based on its high molecular weight ($M_n > 1,000$ Da).

No data on the skin or eye irritation potential of the notified polymer were provided. The notified polymer is a polycarboxylate derived from natural fatty acids and can therefore potentially enhance the dermal absorption of other chemicals in formulated products. Additionally, the notified polymer is similar to polymers that may cause defatting of the skin and result in skin dryness and irritation after prolonged exposure.

Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

There are no toxicological data available for the notified polymer. The notified polymer has no structural alerts that suggest it may be hazardous to human health and toxicological data featured in the provided MSDS for an analogous chemical also indicates it should be of low toxicity. The identity of the analogue was not disclosed, therefore the relevance of the data cannot be considered.

Workers may potentially be at risk of irritating effects to the skin from repeated exposure when handling products containing the notified polymer. This may occur during the reformulation, or the repair and use of industrial machinery to which lubricants containing the notified polymer are added. Workers may potentially be exposed to the notified polymer by inhalation when used as a metal working fluid as mists may be generated.

The risk is expected to be minimised by the use of largely enclosed and automated processes, exhaust extraction and use of appropriate PPE including protective clothing, impervious gloves, and eye protection.

Provided the stated control measures are in place to limit exposure, the risk of the notified polymer to the health of workers is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer and the finished products containing it are intended for industrial application only, hence public exposure is not expected. Therefore, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as products for reformulation into lubricant oils. Significant release of the notified polymer to the environment is not expected during transport and storage except in the unlikely event of accidental spills or leaks.

Any notified polymer spilled during reformulation is expected to be sent to on-site waste treatment facilities. At the on-site waste treatment facilities, residues of the notified polymer will be separated from the aqueous waste stream. The aqueous waste undergoes further treatment involving pond aeration and biological treatment before being released to the sewage system. The remaining non-aqueous waste is expected to be disposed of according to local regulations. As a result of these treatments, greater than 90% removal of the notified polymer is estimated by the notifier. Therefore, the accidental release from reformulation of the notified polymer and finished oils is unlikely to be significant.

RELEASE OF CHEMICAL FROM USE

The finished products containing the notified polymer will be used as a component of metalworking fluids, hydraulic fluids and gear oils. It will be used at industrial sites. The only release during its use may come from spills when pouring lubricant into the machinery reservoir or leaks from the machinery, which is expected to be negligible.

Metalworking fluids containing the notified polymer will have an initial loading into the machinery and the fluid will be recycled within the machinery until it requires changing. Spent fluid will be drained from the machinery sump and will be sent for waste disposal by a professional contractor. The fluid is likely to be incinerated or recycled (150 kg/year). Spills, leaks and residues in empty containers (50 kg/year) will be sent for incineration or disposed to landfill.

The notified polymer will be used as hydraulic fluids and lubricant oils. It will be used in enclosed systems which will require initial loading and top-up. At the end of life, the fluids will be drained from the machinery for disposal. The main method of disposal will be by recycling or incineration. Some of the residual oil within the machinery will have the same fate as the machinery which may be recycled as scrap metal or disposed of to landfill. When used in greases, the notified polymer is likely to have a similar fate.

RELEASE OF CHEMICAL FROM DISPOSAL

During reformulation, empty import drums containing residues of the notified polymer (0.1% of the total import volume) are expected to be steam cleaned, with the residual waste being sent to an on-site wastewater treatment facility. Assuming 0.1% of the notified polymer remains in the empty drums after use, 50 kg/year (50 tonnes/year \times 0.1%) of the notified polymer will be sent to the on-site waste treatment. It is estimated that > 90% of the notified polymer is expected to be removed during waste treatment processes. Therefore, the amount of the notified polymer released to sewer from the cleaning of empty drums is estimated to be 5 kg/year (10% of 50 kg = 5 kg). The wastewater will be further treated at the sewage treatment plants. Therefore, the release of the notified polymer to surface waters is expected to be limited from the cleaning of empty drums.

7.1.2. Environmental Fate

The notified polymer is readily biodegradable in the environment (69% biodegraded after 28 days). Most of the notified polymer is expected to be thermally decomposed during use, recycled or re-refined.

A very small amount of the notified polymer from cleaning of empty drums is expected to be released to sewer. In sewage treatment plants, up to 90% of the notified polymer is expected to partition to sludge due to its very low water solubility and high estimated adsorption/desorption coefficient (log K_{oc}). Any notified polymer released to surface water is expected to partition to sediment based on its limited water solubility and high log

Koc. The notified polymer is not expected to be bioaccumulative due to its high molecular weight. It is also not expected to be bioavailable as it has low water solubility and anticipated limited release to the aquatic environment. Notified polymer sent to landfill is not expected to be mobile. It will slowly degrade by abiotic and biotic processes, or thermally decomposed during use, to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be present at significant concentrations in the aquatic environment because of the very low potential for direct release to surface waters when used in metalworking fluids, hydraulic fluids and gear oils. A Predicted Environmental Concentration (PEC) has therefore not been calculated.

7.2. Environmental Effects Assessment

The calculated ECOSAR data predicts that the notified polymer has no toxicological effects at the limit of its water solubility (US EPA, 2012). Therefore, the notified chemical is not expected to be harmful at the limit of its water solubility, and is not be formally classified under the Globally Harmonised System of Classification of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

No toxicity effects are to be expected at the limit of water solubility for the notified polymer, and therefore the predicted no-effect concentration (PNEC) cannot be calculated.

7.3. Environmental Risk Assessment

As no toxicity effects are to be expected at the limit of water solubility for the notified polymer, the Predicted No-Effect Concentration (PNEC) cannot be calculated. Therefore, based on the use pattern and low potential for aquatic exposure, the notified polymer is not expected to pose an unreasonable risk to the environment when it is used as proposed.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS**C.1. Environmental Fate****C.1.1. Ready biodegradability**

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO ₂ Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Dichloromethane
Analytical Monitoring	Total Organic Carbon (TOC)
Remarks - Method	The test was conducted according to the above mentioned OECD test guidelines. No significant deviations from the test guidelines were reported.
	The stock solution of the test substance was prepared by dissolving 1,253.8 mg of test substance in 25 mL of dichloromethane.

RESULTS

<i>Test substance</i>		<i>Sodium benzoate</i>	
<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
6	13	6	71
9	21.5	9	75
14	36.5	14	80
29	69	29	86

Remarks - Results

All validity criteria for the test were satisfied. The reference control reached the pass level of 60% after 4 days. The toxicity control exceeded 25% biodegradation (required by guideline) showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance was 69% within the 28 days test period.

The degree of degradation of the test substance at the end of the 10-day window was 28%. However, the 10-day window was not applied to interpret the results of the test as the test substance was considered to be a complex, multicomponent substance with structurally similar constituents. Sequential biodegradation of the individual structures of the notified polymer is expected. Therefore, the test substance is readily biodegradable according to the OECD (301 B) guideline.

The results obtained with the toxicity control indicated that there was no toxicity of the test substance towards micro-organisms at the concentration used within the test.

CONCLUSION
TEST FACILITY

The notified chemical is readily biodegradable.
SGS (2013).

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