File No: LTD/1751

July 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Z-138

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:

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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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/1751	Lubrizol International Inc.	Z-138	ND*	≤ 80 tonnes per annum	Dispersant in UV curable inks and coatings

*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
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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - Closed 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 as introduced and reformulated for use:
  - Avoid skin contact
  - Use respiratory protection if mists/aerosols are generated

- 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 as introduced and reformulated for use:
  - Coveralls
  - Impervious gloves
  - Goggles

  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.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by 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 component of UV lithographic and flexographic inks and coatings 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)
Lubrizol International, Inc. (ABN: 52 073 495 603)
28 River Street, P.O. Box 6445,
Silverwater NSW 2128

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 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 (excluding specific gravity and flash point).

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2013)
Canada (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Z-138

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

ANALYTICAL DATA
Reference NMR, IR, GPC, UV-Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

DEGRADATION PRODUCTS
None Known

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	Value	Data Source/Justification
Melting Point/ Boiling Point	Not determined	Expected to decompose before boiling at > 200 °C
Density	1020 kg/m^3 at 25 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight
Water Solubility	Not determined	The notified polymer may be dispersible due to the presence of hydrophilic anionic and potential cationic functional groups

Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, significant hydrolysis is not expected in the environment pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer has a structure characteristic of a surfactant. Therefore, it may partition in the n-octanol/water inter phase.
Adsorption/Desorption	Not determined	It may adsorb on the surface of particles suspended in water phase given the structure is characteristic of a surfactant and has potential cationic functional groups.
Dissociation Constant	Not determined	It is expected to be ionised in the environment given the presence of dissociable functional groups
Particle Size	Not determined	Liquid at 20 °C
Flash Point	> 186 °C	(M)SDS
Autoignition Temperature	Not determined	Expected to have a high autoignition temperature, based on flash point.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

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

Physical hazard classification
Based on the submitted physico-chemical 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 into Australia as the neat form by sea.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0-20	10-30	20-40	30-75	40-80

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer as the neat form in 20 or 180 kg steel drums will be transported by road and rail from the port to the warehouse. After reformulation, the reformulated inks and coatings will be stored and transported in HDPE 20 L pails and 200 L drums.

USE
The notified polymer will be used as a polymeric dispersant at < 15% concentrations in UV curable lithographic and flexographic inks and coatings.

OPERATION DESCRIPTION
The notified polymer will not be manufactured in Australia. It will be imported and reformulated and repackaged at ink or coatings manufacturing sites.

Reformulation/Repackaging
The notified polymer will be manually weighed from the storage drums into a stainless steel blending tank. It will be mixed with other additives such as UV curable monomers and pigments to produce the final ink or coating formulation. The final product containing < 15% concentration of notified polymer will be then fed into containers by gravity through a filter and filling lines. Samples will be taking and tested for quality control by laboratory technicians.

Ink and Coating Application/End-Use
The reservoirs of the ink and coating equipment will be filled manually or through a pump. The application process following charging the equipment with the formulated product is fully automated. The formulated ink or coating product containing the notified polymer (<15%) will be applied to metal, paper or plastic substrates by industrial standard printing and coating techniques and will be cured by exposure to UV light.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	2-3	10-15
Coating/Ink Blending operators	8	50
Laboratory technicians	1	20
Coating/Ink Application	4	260

EXPOSURE DETAILS
Transport and warehousing
Workers are not expected to be exposed to the neat notified polymer or ink/coating formulations containing the notified polymer (at <15%) except in the event of an accident where the packaging is breached.

Ink and coating formulations
Dermal and ocular exposure to the neat notified polymer or formulated polymer at <15% may occur during manually weighing, charging the blending vessels or sampling process, or during cleaning. Inhalation exposure to the notified polymer during reformulation including blending process is unlikely due to the expected low vapour pressure of the notified polymer and use of closed processes.

Ink and coating applications
Dermal and ocular exposure to the notified polymer at < 15% concentration may occur during filling the ink or coating equipment reservoirs, scraping residuals from used containers and cleaning and maintaining the equipment. Inhalation exposure is not expected unless mists/aerosols are generated during the printing/coating processes.

Exposure is not anticipated for those workers who might make dermal contact with the notified polymer when handling cured end products, as the notified polymer will be incorporated into the polymer matrix and not expected to be bioavailable.

6.1.2. Public Exposure
The ink and coating products containing the notified polymer will not be sold to the public. Once cured by exposure to UV light onto the substrate, the notified polymer is not expected to be bioavailable as it will be incorporated into the polymer matrix once dried or cured.

6.2. Human Health Effects Assessment

No toxicity data were submitted on the notified polymer. It is expected to be surface active and its high molecular weight and low levels of species <1000 would limit dermal absorption. The MSDS of the notified polymer states that data on similar materials indicate that it is expected to have low acute oral and dermal

toxicity and may have some eye irritation potential. The polymer contains functional groups that may produce eye and skin irritation and skin sensitisation, and these effects cannot be ruled out.

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
Due to the limited toxicity data available, the hazard profile of the notified polymer is not conclusive. The notified polymer may have the potential for skin and eye irritation and skin sensitisation.

Dermal and ocular exposure of workers to the notified polymer will be minimised through the use of closed systems where possible and PPE such as coveralls, impervious gloves and goggles. Respiratory protection would be needed only if mists/aerosols were generated. Dermal exposure is not expected for workers handling printed substrates as the notified polymer will be bound within a print matrix and is not expected to be bioavailable.

The risk to workers is not considered to be unreasonable if such controls are in place.

6.3.2. Public Health
The ink and coating products containing the notified polymer will be for industrial use only and will not be sold to the public. No exposure is expected from the dried printed or coated materials as the notified polymer is not expected to be bioavailable. Therefore, based on very low exposure potential, the notified polymer does not pose an unreasonable risk to the public.

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 and further reformulated into UV-curable ink and coating products for application to metal, paper and plastic substrates.

The notifier has estimated that approximately 0.5% of the annual introduction volume of notified polymer will be lost as result of spillages during ink and coating manufacturing processes. It is expected that any spillages will be collected and disposed of to landfill. Up to 1% of the annual import volume of the notified polymer is expected to remain in import drums that are expected to be collected by licensed waste contractors. After treatment to remove organic solvents and insoluble substances by the licensed waste contractors, it is expected that residue from the drums will be released to sewage treatment plants.

RELEASE OF CHEMICAL FROM USE

Since UV curing will be carried out after coating, the application of the coating products containing the notified polymer will be done only at industrial sites. For roller or dipping coating, the waste is expected to be about 2% of the applied volume, and is expected to be captured or collected for disposal to landfill as solid wastes. Similarly, the wastage resulting from the application of inks to surfaces by the use of rollers is expected to be up to 2% of the applied volume, which is expected to be collected for disposal to landfill. An extra 2% of the applied volume may be generated as a result of the clean-up of containers and application equipment, which is expected to be disposed of to sewage for the worst case scenario situations. Once cured after application, the notified polymer is expected to be trapped in the inert coating film, and is not expected to be released to the environment.

RELEASE OF CHEMICAL FROM DISPOSAL

No significant release of the notified polymer to the sewer system from the reformulation site and use is expected. Some of the notified polymer may be collected as wastes for disposal to landfill or be released to

sewer. Most of the notified polymer is expected to be associated with metal, paper or plastic substrates and share the fate of the substrates, which is most likely landfill at the end of the useful life. The exception is that 50% of the waste paper is expected to be recycled.

7.1.2. Environmental Fate

No environmental fate data were submitted. The notified polymer is not expected to be bioavailable given its high molecular weight (> 1000 Da).
Up to 3% of the imported notified polymer is expected to be disposed of to sewer from reformulation and use. Most of the notified polymer is expected to be immobilised within a UV-cured polymeric film on coated articles after printing and coating applications. The notified polymer will be disposed of along with the used article at the end of its useful life, which, in the majority of cases, will be to landfill. In cases where inks containing the notified polymer are used on paper, there is some potential for release of the notified polymer during the de-inking stage of paper recycling. During paper recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The notified polymer may partition to the supernatant water, which is expected to be released to the sewer, based on its expected property as a dispersant. Due to its surface activity, high molecular weight (> 1000 Da) and predominant proportion of hydrophobic components, a significant portion of the notified polymer may partition to sludge during paper recycling and sewage treatment plants (STPs) processes. Sludge containing the notified polymer is expected to be disposed of to landfill or applied to soil for remediation of agricultural land.

In landfill or water, the notified polymer is expected to undergo biotic and abiotic degradation, finally forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is for application to metal, paper and plastic substrates. It is unclear at what percentage of the imported polymer will be used for paper-associated printing/coating. It is commonly assumed that 50% of the waste paper is recycled after use. Assuming 100% of the notified polymer will be used for paper for the worst case scenario, 50% of the imported notified polymer is expected to undergo paper recycling process. The Predicted Environmental Concentration (PEC) was calculated assuming that the 90% of the notified polymer is removed from influent during STPs processes by adsorption to sediment and sludge (Boethling & Nabholz, 1997)), with the sludge eventually disposed of to landfill or re-used for soil remediation. It was assumed that release of the notified polymer occurs from recycling processes over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	80,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	40,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	153.85	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	**Mitigation**
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	3.4	µg/L
PEC - Ocean:	0.34	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 306.2 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 1500 kg/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 2.04 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 10.2 mg/kg and 20.4 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/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/m^3). Using these assumptions, irrigation with a concentration of 3.4 µg/L may potentially result in a soil concentration of approximately 22.7 µg/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 113 µg/kg and 227 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The toxicity to aquatic organisms was calculated using the US EPA Interpretive Assistance Structure-Activity Relationship (SAR) for polymers containing cationic components (US EPA 2013).

Endpoint	*Result*	*Assessment Conclusion*
Acute Toxicity		
Fish Toxicity (96 hour)	LC50 = 41.47 mg/L	Harmful
Daphnia Toxicity (48 hour)	EC50 = 37.86 mg/L	Harmful
Algal Toxicity (96 hour)	EC50 = 6.59 mg/L	Toxic
Chronic Toxicity		
Fish Toxicity	ChV = 2.3 mg/L	Not harmful
Daphnia Toxicity	ChV = 2.7 mg/L	Not harmful
Algae Toxicity	ChV = 1.73 mg/L	Not harmful

Based on the worst-case SAR, the notified polymers are toxic to aquatic organisms in environmental waters with typical levels of total organic carbon. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general predictions of the likely environmental effects of the polymers. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymers to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The most sensitive ecotoxicological endpoint for the notified polymers was the calculated chronic value (ChV) for algae. This endpoint was used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 50 was used as a worst-case calculated chronic endpoint was used for determination of the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ChV (algae)	1.73	mg/L
Assessment Factor	50	
PNEC:	34.6	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	3.4	34.6	**0.1**
Q - Ocean	0.34	34.6	**0.01**

The Risk Quotient (RQ = PEC/PNEC) was calculated to be < 1, indicating the notified polymer will not be present at ecotoxicologically significant concentrations in surface waters.
The notified polymer is not expected to pose an unacceptable risk to the environment based on the assessed use pattern.

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