

File No PLC/712

October 2007

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

FULL PUBLIC REPORT

Polymer in Polyloc

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888.
Website:	www.nicnas.gov.au

**Director
NICNAS**

TABLE OF CONTENTS

FULL PUBLIC REPORT	3
1. APPLICANT AND NOTIFICATION DETAILS	3
2. IDENTITY OF CHEMICAL	3
3. PLC CRITERIA JUSTIFICATION	3
4. PHYSICAL AND CHEMICAL PROPERTIES	4
5. INTRODUCTION AND USE INFORMATION	4
6. HUMAN HEALTH IMPLICATIONS	6
Toxicological Hazard Characterisation	6
Human Health Risk Assessment	6
7. ENVIRONMENTAL IMPLICATIONS	6
Exposure Assessment	6
Environmental Hazard Characterisation	7
Environmental Risk Assessment	7
8. MATERIAL SAFETY DATA SHEET	8
9. CONCLUSIONS AND REGULATORY OBLIGATIONS	8
Level of Concern for Occupational Health and Safety	8
Level of Concern for Public Health	8
Level of Concern for the Environment	8
Recommendations	8
Regulatory Obligations	8

FULL PUBLIC REPORT

Polymer in Polyloc

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Becker Underwood Pty Ltd (ABN: 25 107 914 563)
RMB 1084 Pacific Highway
Somersby NSW 2250

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Residual Monomers/Impurities, Use Details, Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polyloc

% of Low MW Species < 1000	< 15%
% of Low MW Species < 500	< 10%

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	> 1000 Da
--------------------------------------	-----------

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

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	Straw yellow liquid with slight ammonia odour
Melting Point/Glass Transition Temp	100°C
Density	1098 kg/m ³ at 4°C
Water Solubility	Completely soluble in water (> 360g/L)
Dissociation Constant	Not determined. The notified polymer contains anionic functionality, which is expected to have a pKa of 3-4.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use. Thermal decomposition products are: carbon monoxide, carbon dioxide and ammonia.

Comments

The above information was cited in the MSDS for a < 40% aqueous solution of the notified polymer.

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>
<i>Tonnes</i>	< 10	< 10	< 10	< 10	< 10

USE AND MODE OF INTRODUCTION AND DISPOSAL

Use

The notified polymer will be a component of an emulsion that will be applied to agricultural seeds to assist in binding (maintaining structural integrity of the seeds), flowability and visual appearance of the seeds.

Based on the information provided by the notifier on the use of the notified polymer, the notified polymer was deemed to be excluded from registration with the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Mode of Introduction and Operation description

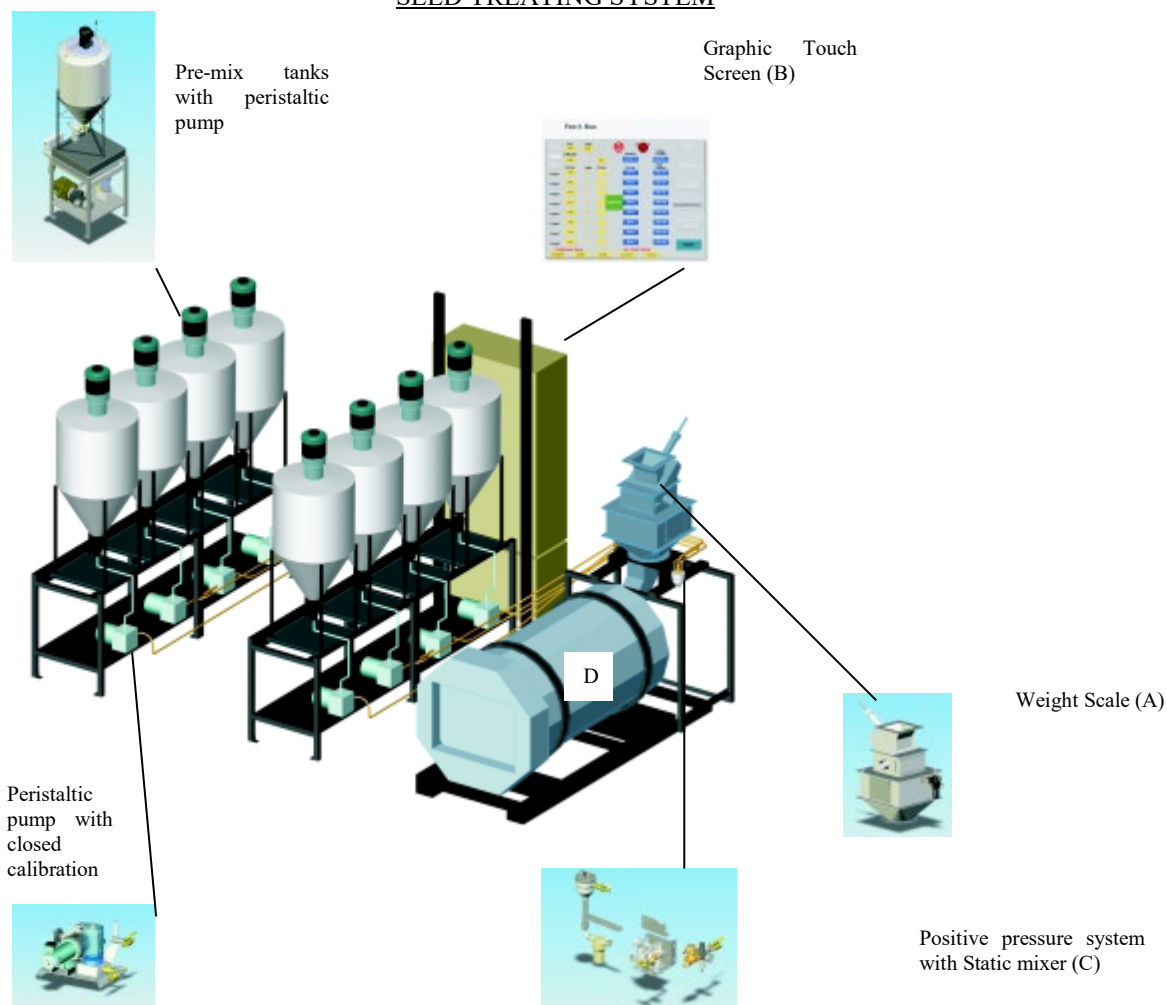
Polyloc containing the notified polymer will not be reformulated in Australia. The notified polymer will be imported in 200 L metal drums as an aqueous emulsion at < 15% concentration. The imported product will be transported by road to the seed treatment plant and stored before use.

Seed treatment process

At the seed treatment plant, two plant operators will transfer 200 L drums of Polyloc to the premix tank via a metered pump for storage before seed treatment process takes place.

The process diagram below describes a typical seed coating process.

SEED TREATING SYSTEM



The plant operator will manually pour seed from sacks into a weight scale (A). The scale recognises the seed weight and activates the selected pump through the control panel (B).

Control panel (B) activates the operator selected pump(s) (1-8) for up to eight different products. In this case, it will be the film coating pump, containing the Polyloc (containing the notified polymer at < 15% concentration)

Selected pump(s) (1-8) will deliver products to the positive pressure system with static mixer (C). The static mixer will be activated at exactly the same time as the pump(s) through the electronic control panel (B). The notified polymer will then be thoroughly mixed and applied under pressure through one of several atomising systems. The atomising systems will uniformly apply the proper amount of seed treatment product to each seed.

Treated seed will then be mixed in the polishing drum (D) for a finalised coverage, airing and drying process.

Finished, coated seeds will then be discharged into a bagging bin. The seed will be packaged into sacks through an automatic pump.

End use

End-users of the end product will be farmers growing high volumes products such as corn and wheat around Australia.

6. HUMAN HEALTH IMPLICATIONS

Toxicological Hazard Characterisation

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

Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Transport and storage

Exposure to the polymer is unlikely during transportation and storage. Exposure may result if accidental spills or leaks occur. No specific PPE will be worn under normal operating conditions.

Seed treatment process

Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer, for example from drips and spills when connecting and disconnecting pumps to fill premix tanks. However, exposure to significant amounts of the notified polymer will be limited because of the semi automated processes, and the engineering controls and personal protective equipment worn by workers.

End use

Farmers growing high volumes products such as corn and wheat will make dermal contact with treated seeds containing the notified polymer. However, the exposure to the notified polymer will be limited because the coating will be dried.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the presumed low intrinsic hazard of the polymer.

PUBLIC HEALTH

Public exposure to the notified polymer is not expected, as it is only intended to be used by farmers growing high volume products such as corn and wheat, and will not be available to the public in its imported form. Seeds coated with the notified polymer may be sold to the public through retailers, such as domestic nurseries. Members of the public may make dermal contact with seeds treated with coatings containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is presumed to be of low hazard.

7. ENVIRONMENTAL IMPLICATIONS

Exposure Assessment

ENVIRONMENTAL RELEASE**RELEASE OF CHEMICAL AT SITE:**

Release at seed treatment site to the environment may occur in the unlikely event of an accident during transport or an accidental leak. It is estimated that a maximum of 1% of the notified polymer (~ 100 kg per year of notified polymer) would be lost during spillage. Spills are contained and soaked up with inert absorbent material (sand, diatomite, acid binders, universal binders or sawdust) and placed in a sealable container and disposed of to landfill.

The empty drums will be collected by a licensed waste contractor for disposal to landfill. Residues in drums are expected to be approximately 50 kg per annum based on annual import volumes. There will be no release of the notified polymer to sewer during seed treatment.

The notified polymer is expected to be released to soil during/after the sowing of seeds. According to the label a variety of seeds can be coated, ranging from large ones such as corn and sunflowers, medium seeds such as wheat and soybeans to very small seeds such as cotton and canola.

The rate of application varies ranging from 50 to 600 ml per 100 kg of seeds i.e. 5-60 g (assuming a 10% content of the notified polymer and a specific gravity of 1.098 g/mL). This equates to 0.005-0.07% w/w.

There was no information in the submission on the rate of sowing of seeds but available information indicates canola, to which the highest range is added (300-600 mL per 100 kg), is sown at a rate of 3-5 kg/ha between 2-4 cm deep. At the maximum mixing and sowing rate this equates to 3 g/ha. Assuming this spreads equally through the first 5 cm of the soil, this equates to 0.004 mg/kg. (While no adsorption/desorption data are available, the notifier indicates the notified polymer is designed to adsorb on to seeds to protect the seed. Thus it is likely there will be pockets of higher concentration if adsorption is maintained).

ENVIRONMENTAL FATE

Given its use pattern and properties, the notified polymer will mainly become associated with the soil following release to the environment, where it will be exposed to such processes as hydrolysis, microbial metabolism and absorptive interactions.

Environmental Hazard Characterisation

No ecotoxicological data were submitted.

Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid 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.

As noted above the main exposure will be to the soil environment. However, the notifier has indicated no test results for soil invertebrates such as earthworms are available, or indeed to birds which may ingest treated seeds.

Environmental Risk Assessment

No aquatic exposure is anticipated during end use of the notified polymer. It is envisaged that up to 2% waste would be generated from the end-use. These wastes would be collected by licensed waste contractors. It is expected that practically all of the waste generated from end users will be disposed of in approved landfills. In landfill, the solid wastes will not be mobile and will degrade slowly and not pose a significant risk to the environment.

Based on the proposed use pattern, it is expected that sufficient uncontaminated soil will be available for invertebrates to recover or shelter.

The environmental concentration of the notified polymer is relatively low (max 0.07%) and from the high molecular weight of the notified polymer, it would not be expected to be bioavailable or absorb through biological membranes. Therefore the risk to the soil environment is considered to be

acceptable.

8. MATERIAL SAFETY DATA SHEET

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

9. CONCLUSIONS AND REGULATORY OBLIGATIONS

Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

Level of Concern for Public Health

There is No Significant Concern to public health when used in the proposed manner.

Level of Concern for the Environment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.
- Empty containers should be sent to local waste disposal facilities.

Emergency procedures

- Spills/release of the notified polymer should be handled by absorbing with sand and put into suitable container for 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 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 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 chemical has changed from being a component of a seed coating, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 10 tonnes per annum, 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.