

File No EX/133 (PLC/589)

December 2009

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

FULL PUBLIC REPORT

Polymer in Liquitint Yellow LP

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 Heritage.

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**Director
NICNAS**

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Polymer in Liquitint Yellow LP

This assessment report is for an extension of original assessment certificate for Polymer in Liquitint Yellow LP. Based on the submission of new information by the extension notifier, some sections of the original assessment report for Butanedioic acid, Polymer in Liquitint Yellow LP have been modified. These modifications have been made under the heading 'Extension Applicant' in the respective sections.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Holders of the Original Assessment Certificates (Nos. 2272 and 2273, PLC/589):

Walk Off Mats Asia Pacific Pty Ltd (ABN: 14 002 708 830)

U7/95 O'Sullivan Beach Rd,
Lonsdale, South Australia, 5160

and

Albright & Wilson (ABN: 36 004 234 137)

22 Davis Rd,
Wetherill Park, NSW, 2164

Applicant for an Extension of the Original Assessment Certificate:

Colin Campbell (Chemicals) Pty Ltd (ABN 29 000 045 590)

5 Blackfriar Place
Wetherill Park, NSW 2164

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, Import Volume, and Site of Reformulation

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)

Low Volume Chemical Permit

NOTIFICATION IN OTHER COUNTRIES

US PMN (1986)

Korea (1999)

China (2002)

New Zealand (1998)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Polymer in Liquitint® Yellow LP

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) >1000

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains a potentially cationic functional group with an FGEW < 5000, however supporting test data showed the functional group was not potentially cationic in the environmentally relevant pH range.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met (yes/no/not applicable)</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

The following physical chemical data was provided for an aqueous solution (up to 50% of the notified polymer)

Appearance at 20°C and 101.3 kPa	Dark yellow liquid
Freezing Point	0°C
Boiling Point	100°C
Density	1020 kg/m ³ (estimation, temperature unspecified)
Water Solubility	Highly soluble (product is 50% aqueous solution)
Dissociation Constant	pKa = <2.0 based on no decrease in UV absorptivity until the pH falls below 2.
Hydrolysis as a function of pH	Based upon testing at elevated temperatures. T _{1/2} at pH 4.0 = 3.19 years at 20°C. T _{1/2} at pH 7.0 = 27.13 days at 20°C. T _{1/2} at pH 9.0 = 3.54 days at 20°C.
Partition Coefficient (n-octanol/water)	log K _{OW} = 1.380 based upon HPLC Method and Linear Regression.
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>
<i>Tonnes (PLC/589)</i>	<1	<1	<1	<1	<1
<i>Extension</i>	10	10	10	10	10

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The notified polymer will not be manufactured in Australia. The product Liquitinit® Yellow LP containing the notified polymer at up to 50% will be imported in 18 kg drums. The notified polymer will be transported by road to storage facilities within NSW prior to distribution by road to customers in NSW.

Reformulation/manufacture processes

The product containing the notified polymer (up to 50%) will be added typically by automated means whereby the drum is lanced and the liquid transferred to either a storage tank or directly to the blending tank. After blending is complete the resulting products containing up to 0.1% of the notified chemical are packaged by automated means. Workers will wear personal protective equipment such as gloves, coveralls and safety glasses in accordance with the MSDS.

Extension Applicant:

The imported product containing the notified polymer at a concentration of 50% in aqueous solution will be diluted with water and other components to form the spray that will be applied to the recreational turf. Workers will wear personal protective equipment such as gloves, coveralls and safety glasses in accordance with the MSDS.

Use

The notified polymer is used as a colourant in household soaps and detergents. The notified polymer is present in the consumer products at up to 0.1%, typically the notified polymer would be present at 0.0005–0.01%.

Extension Applicant:

The notified polymer will be used as a colourant on recreational turf at concentrations of 0.1%. The spray containing the notified polymer will be applied to the recreational turf through commercial spray application methods.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is limited because of the fully automated processes, and personal protective equipment worn by workers. Up to 10 workers at one site may be involved in reformulation for 8h/day, 50 days per year.

Extension Applicant:

There is potential for ocular and dermal exposure to the notified polymer (at 50%) during the dilution of the imported product. Inhalation, ocular and dermal exposure to the notified polymer (at 0.1%) may also occur during the application of the spray containing it to recreational turf. Significant exposure is not expected given the expected use of PPE and low concentration of the notified polymer in the spray.

PUBLIC EXPOSURE

The notified polymer will not be sold to the public except in the form of finished products. There is potential for extensive public exposure to products containing the notified polymer at concentrations <0.1% (typically 0.0005%–0.01%), such as household soaps and detergents (fabric softeners and cleaning solutions). However exposure would be minimised as the notified polymer will easily wash away from skin and no residue is expected to remain in textile garments due to the high water solubility.

Extension Applicant:

Dermal exposure to the notified polymer by the public may occur when using recreational turf to which it has been applied. Exposure is expected to be low due to the low concentration (0.1%) at which it will be applied to recreational turf.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on products containing the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral*	LD50 >5000 mg/kg bw	no	no	Not specified. No significant deviations from OECD TG 401
2. Rabbit, skin irritation*	non-irritating	no	no	US TSCA EPA No. 158.81-5 analogous to OECD TG 404
3. Skin sensitisation - adjuvant test/non-adjuvant test†	no evidence of sensitisation.	no	no	OECD TG 406 Maximisation tests)

*Test conducted on a 30% aqueous solution of the notified polymer

†Test conducted on a 50% aqueous solution of the notified polymer

All results were indicative of low hazard.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Although exposure to the notified polymer could occur during reformulation, the risk to workers is considered to be low due to the engineering controls and personal protective equipment recommended combined with the intrinsic low hazard of the notified polymer.

Extension Applicant:

Although exposure to the notified polymer could occur during the dilution and application of the product containing the notified polymer, the risk to workers is not considered unacceptable given the use of PPE and its assumed low hazard.

PUBLIC HEALTH

The notified polymer will not be available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be low because the notified polymer is of low hazard, will easily wash away from skin, no residue is expected to remain in textile garments due to the high water solubility.

The risk to public health is considered to be low due to the limited predicted exposure and the intrinsic low hazard of the notified polymer.

Extension Applicant:

There is potential for dermal exposure by the public to recreational turf that has been sprayed with products containing the notified polymer. However, given the low concentration (0.1%) and assumed low hazard of the notified polymer, the risk to public health is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

Environmental release of the notified polymer is summarised in the following table.

<i>Source of release</i>	<i>% Annual Import Volume</i>	<i>Released to</i>
Residual within Import Containers	<1%	Landfill
Accidental Spills	<2%	Incinerator
Reformulation equipment cleaning	<1%	Trade Waste Sewer
Residual within consumer containers	<2%	Landfill
Use of formulated products containing the notified polymer.	>94%	Domestic Sewer

ENVIRONMENTAL FATE

Notified polymer that is disposed of by incineration is expected to be thermally decomposed to form simple oxides of carbon, nitrogen and hydrogen.

Notified polymer that is disposed to sewer is expected to remain partitioned to the aquatic compartment. The notified polymer is expected to eventually degrade via biotic and abiotic mechanisms to simple compounds.

Notified polymer that is disposed to landfill may be mobile, due to its solubility in water. Over time, the notified polymer is expected to degrade via biotic and abiotic mechanisms to simple compounds.

7.2. Environmental Hazard Characterisation

Environmental endpoints observed in testing conducted on the notified polymer are summarised in the following table.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Daphnia Toxicity	EC50 >100 mg/L	no	OPPTS 850.1010
Inherent Biodegradability	Inherent biodegradability	60% degraded under an extended test period of 39 d	OECD 302B

The modified Zahn-Wellens inherent biodegradability test determined that 58% had degraded after 28 days. Therefore, the notified polymer may be classified as inherently biodegradable.

7.3. Environmental Risk Assessment

Since most of the polymer will be washed into the sewer, under a worst case scenario, with no removal of the notified polymer in the sewage treatment plant, the resultant Predicted Environmental Concentration (PEC) in sewage effluent on a nationwide basis, Predicted No-Effect Concentration (PNEC) and Risk Assessment (Q) are estimated as follows:

<i>Predicted Environmental Concentration (PEC)</i>			
Annual quantity of chemical released to sewer	1,000	kg/year	
Days per year where release occurs	365	days/year	
<i>Daily chemical release:</i>	2.74	kg/day	
Water use	200.0	L/person/day	
Population of Australia (Millions)	20.438	million	
<i>Daily effluent production:</i>	4,088	ML	
Dilution Factor - River	1.0		
Dilution Factor - Ocean	10.0		
<i>PEC - River:</i>	0.67	µg/L	
<i>PEC - Ocean:</i>	0.07	µg/L	
<i>Predicted No-Effect Concentration (PNEC)</i>			
Lowest LC50/EC50 (Daphnia)	>100.00	mg/L	
Assessment Factor	1,000.00		
<i>PNEC:</i>	>100.00	µg/L	
<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	0.67	>100	<0.007
Q - Ocean:	0.07	>100	<0.001

As the PEC/PNEC ratio is considerably less than 1 for both river and ocean, there should be a low risk to aquatic organisms.

Extension applicant:

The circumstances in the extension application are not expected to impact on the original environment risk assessment. Although there will be an increase in volume to 10 tonnes per annum,

the risk quotients will still be less than one. Therefore there are no changes required in the risk assessment.

8. CONCLUSIONS

8.1. 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.

8.2. Level of Concern for Public Health

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

8.3. Level of Concern for the Environment

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

8.4. Risk assessment (extension applicant)

In contrast to the original notifier, the extension applicant will import the notified polymer at higher volumes for a different proposed use. However these changes in circumstances in the extension application are not expected to impact on the original human health and environment risk assessment.

9. MATERIAL SAFETY DATA SHEET

9.1. 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.

Extension applicant:

The MSDS of the introduced product containing the notified polymer provided by the extension applicant has been reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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 by licensed waste removal to landfill.

Emergency procedures

- Spills and accidental release of the notified polymer should be handled by using absorbent inert material. The inert material should be placed in containers and disposed of in accordance with government regulations.

10.1. Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 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 subsection 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.