File No: LTD/1472

July 2010

NATIONAL INDUSTRIAL POLYMERS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Harmide RB-207

This Assessment has been compiled in accordance with the provisions of the *Industrial Polymers (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Polymers 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, Water, Heritage and the Arts.

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

Harmide RB-207

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chemcolour Industries Australia Pty Ltd (ABN 70 125 602 271)
Monash Business Park, 20-22 Gardiner Rd
NOTTING HILL VIC 3168

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: polymer name, other names, CAS number, molecular and structural formulae, polymer constituents.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Hydrolysis as a Function of pH, Partition Co-efficient, Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Japan

2. IDENTITY OF POLYMER

MARKETING NAME(S)
Harmide RB-207 (product containing the notified polymer at 20% concentration)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn)	437,307 Da.
Weight Average Molecular Weight (Mw)	3.558×10^6 Da.
Polydispersity Index (Mw/Mn)	8.14
% of Low MW Species < 1000 Da	0%
% of Low MW Species < 500 Da	0%

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

None

4. PHYSICAL AND CHEMICAL PROPERTIES

The following information on the physical and chemical properties of the notified polymer is based on the product Harmide RB-207 containing the notified polymer at 20% concentration in water. No data were submitted on the notified polymer itself.

APPEARANCE AT 20°C AND 101.3 kPa: Slightly cloudy solution

Property	Value	Data Source/Justification
Freezing Point	0°C	Estimated
Boiling Point	>97°C	Estimated
Density	1070 kg/m^3	MSDS
Vapour Pressure	Not determined	Estimated to be similar to water
Water Solubility	Not determined	The notified polymer is expected to be readily soluble in water based on its use at high concentrations in aqueous products and the established high water solubility of analogous polymers. The notified polymer forms a gel at high concentrations.
Hydrolysis as a Function of pH	Not determined	The notified polymer may hydrolyse slowly under environmental conditions
Partition Coefficient (n-octanol/water)	Not determined	The high molecular weight of the notified polymer indicates it will not cross biological membranes
Adsorption/Desorption	Not determined	Based on its net positive charge the notified polymer is expected to sorb strongly to soil and sediment and have low mobility in the environment
Dissociation Constant	Not determined	The notified polymer is a salt and will be ionised in the environmental pH range (4-9).
Flash Point	Not expected to have a low flash point	Estimated based on structure
Flammability	Not expected to be flammable	Estimated based on structure
Autoignition Temperature	Not expected to autoignite	Estimated based on structure
Explosive Properties	Not expected to be explosive	Estimated based on structure

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer is expected to become cationic in water.

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above does not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED POLYMER (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia but imported at 20% concentration for use as a dry strength agent in the manufacture of paper and paperboard.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3300	3300	3300	3300	3300

PORT OF ENTRY
Brisbane

IDENTITY OF MANUFACTURER/RECIPIENTS
Chemcolour Industries Pty Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in intermediate bulk containers (IBCs) and transported by road to a customer site.

USE
The notified polymer will be used in paper manufacturing at approximately 0.3% concentration to give dry strength to fibres of paper and paperboard.

OPERATION DESCRIPTION
The notified polymer will be imported at 20% concentration in water and transported to customer sites where it will be used in paper manufacturing. At the manufacturing site, the notified polymer will be pumped using an automated system from the import container into a storage tank or directly into the paper manufacturing system along with the pulp. The solution containing the pulp, notified polymer (at 0.3% concentration) and other chemical additives will be mixed, refined, sieved, pressed, dried, sized and spooled onto rollers to produce finished paper products.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
During paper manufacture
Workers may encounter dermal and possibly ocular exposure from drips and spills of the notified polymer at 20% concentration when connecting and disconnecting lines to import containers to pump the notified polymer into the paper manufacturing system. Once pumped into the paper manufacturing system, exposure to the notified polymer at 0.3% concentration will be limited as the system will be closed and operated remotely by computer. Dermal exposure may also occur during maintenance and cleaning of the paper making machines. Workers are expected to wear overalls, face mask, safety glasses, safety shoes and impervious gloves to minimise exposure.

End-use
Office workers will make dermal contact with the dried paper containing notified polymer at 0.3% concentration. Exposure to the notified polymer is expected to be negligible because the notified polymer is present at low concentrations in the paper (0.3%), will be bound within the paper matrix and will not be bioavailable.

6.1.2. Public exposure
The notified polymer is not available for sale to the public. The potential for public exposure to the notified polymer during transport, reformulation and manufacturing of paper is likely to be negligible. The public will make dermal contact with the paper containing the notified polymer. However, this is unlikely to lead to exposure because the notified polymer is present at a low concentration (0.3%) in the paper, will be bound within the paper matrix and will not be bioavailable.

6.2. Human health effects assessment

As no toxicity data were submitted, it is not possible to establish the hazard potential of the notified polymer.

Considering that the notified polymer has a high molecular weight, is water-soluble and cationic, it is not expected to be absorbed by the oral, dermal or inhalation routes.

The notified polymer contains a number of functional groups of concern; with a functional group equivalent weight (FGEW) of 500-1000 Da. The functional group has corrosion/irritation potential (Rorije and Huzelbos (2005), Tsakovska, Netzeva and Worth (2005). However, the corrosion/irritation hazard presented by the notified polymer is not expected to be significant due to the FGEW > 500 Da.

Health hazard classification
In the absence of toxicity data, the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The main concern for workers handling the notified polymer at 20% concentration is the potential for corrosion/irritation to the skin and eyes. The potential for exposure to the notified polymer at 20% concentration is considered to be limited to spills and drips which may occur during connection and disconnection of hoses from the import containers to the paper manufacturing system. Workers are also expected to wear PPE which will further minimise dermal and ocular exposure.

Once fed into the paper manufacturing system, exposure is expected to be limited as the system will be closed and will be operated remotely by computer. Exposure is also expected to be limited during cleaning and maintenance due to the low concentration (0.3%) of the notified polymer and the use of PPE.

Office workers who make dermal contact with paper manufactured using the notified polymer are expected to experience negligible exposure as the notified polymer will be present at a low concentration (0.3%) in the paper, will be bound within the paper matrix and will not be bioavailable.

Overall, the use of PPE during use of the notified polymer as imported at 20% concentration and the low concentration (0.3%) of the notified polymer in subsequent exposure scenarios, is expected to lead to minimal or negligible exposure to workers and therefore, the risks to occupational health and safety are not considered to be unacceptable.

6.3.2. Public health
The public are not expected to be exposed to the notified polymer except through contact with paper manufactured with the notified polymer similar to the scenario described above for office workers. Members of the public who make dermal contact with paper manufactured using the notified polymer are expected to experience negligible exposure as the notified polymer will be present at a low concentration (0.3%) in the paper, will be bound within the paper matrix and will not be bioavailable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF POLYMER AT SITE
The notified polymer will be imported as a product formulated for use (after dilution on site) in a paper manufacturing facility. No significant release of the notified polymer to the environment is expected from transport and storage processes.

RELEASE OF POLYMER FROM USE
At the industrial customers' site, the product containing the notified polymer will be pumped into a storage

tank from where it will be transferred directly into the paper making system. It is assumed that the majority of the notified polymer will adsorb onto the paper fibre during the application processes as it is recirculated in a closed system. The remainder may be released into waste water produced by the manufacturing process. The notified polymer would only be released from the paper mill in the backwater/effluent discharge after treatment.

RELEASE OF POLYMER FROM DISPOSAL

Empty IBCs containing residual notified polymer will enter the second-hand IBC market for reuse through a professional IBC recycling company. It is expected that residues in the import containers would be washed out on-site at the paper mill and the rinsates used in production or treated in the on-site water treatment facility. Alternatively, aqueous rinsates from used IBCs would be washed out at the recycling company facility and the residues discharged to sewer after appropriate on-site water treatment. The losses of notified polymer in container residues are estimated to be < 1% per annum.

It is assumed that 50% of the paper to which the notified polymer is applied will end up in landfill and the remainder will undergo paper recycling processes.

7.1.2 Environmental fate

No environmental fate data were submitted. Since the notified polymer has a molecular weight much greater than 1000 Da. and no significant percentage of low molecular weight constituents, it is not expected to be able to cross biological membranes and therefore will not bioaccumulate.

It is assumed that 50% of the waste paper to which the notified polymer is applied will be recycled domestically. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. The notified polymer released from paper pulp during recycling may partition to the aqueous phase due to the high solubility of the polymer. However, the notified polymer would be expected to be efficiently removed from waste water in waste water treatment plants through adsorption of the cationic polymer to sludge or by flocculation (Boethling and Nabholz, 1997). The notified polymer is therefore expected to be concentrated in the sludge fraction of on-site or municipal waste water treatment plants. Sludge generated during the washing process will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil and sludge due to its cationic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). The notified polymer is expected to undergo slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

A preliminary calculation of the PEC was carried out assuming that 50% of the paper containing the notified polymer would be recycled and released to sewers with no mitigation. The calculation indicated that the PEC > PNEC (Predicted No Effect Concentration), hence a more realistic exposure scenario was calculated such that 90% of the notified polymer released to the sewers was assumed to partition to sludge in STPs due to its net positive charge (Boethling and Nabholz, 1997). The results of the calculation with the mitigation included are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	3,300,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of polymer released to sewer	1,650,000	kg/year
Days per year where release occurs	260	days/year
Daily polymer release:	6346.15	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	90%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	149.95	□g/L

PEC - Ocean:	14.99	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 13495.5 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 polymer may approximate 89.97 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 approximate 449.9 mg/kg and 899.7 mg/kg, respectively.

7.2. Environmental effects assessment

Ecotoxicological endpoints for the notified polymer were calculated based on SAR equations for estimating the toxicity of polycationic polymers (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by toxicity reduction factors (which depend on the cation to anion ratio) and mitigating factors (due to organic carbon in the environment).

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 (96 h) = 268.5 mg/L	Not harmful
Daphnia Toxicity	EC50 (48 h) = 3816.2 mg/L	Not harmful
Algal Toxicity	EC50 (96 h) = 427.7 mg/L	Not harmful

The notified polymer is not expected to be harmful 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 indications of the likely environmental effects of the polymer. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1 Predicted No-Effect Concentration

The most sensitive endpoint from the ecotoxicity calculations on the notified polymer is for fish and this was selected for the calculation of the PNEC below. A conservative assessment factor of 1000 was used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50 (Fish, 96 h, calculated)	268.5	mg/L
Assessment Factor	1000	
PNEC:	268.5	µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	149.95	268.5	0.558
Q - Ocean	14.99	268.5	0.056

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC. The Q value of < 1 indicates the notified polymer is not expected to pose an unacceptable risk to the aquatic environment from its proposed use pattern at the proposed maximum import volume.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

In the absence of toxicity data, the notified polymer cannot be classified as hazardous according to 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 unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced at 20% concentration, in the product Harmide RB-207:
  - Avoid contact with skin and eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced at 20% concentration, in the product Harmide RB-207:
  - Chemical resistant gloves
  - Coveralls
  - Safety glasses

  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.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical 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 polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Polymers (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 Polymer 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(2) of the Act; if

- the function or use of the polymer has changed from a chemical used in paper manufacturing, 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 MSDS of a product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Bibliography

Boethling, RS & Nabholz VJ (1997) Environmental Assessment of polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

Rorije E, Hulzebos EM (2005) Evaluation of (Q)SARs for the prediction of Skin Irritation/Corrosion Potential. Physico-chemical exclusion rules. Report submitted by the National Institute of Public Health and Environment (RIVM) to the European Chemicals Bureau (ECB). Available for download from ECB (http://ecb.jrc.it/QSAR) as of 2008-04-13.

Tsakovska I, Netzeva T & Worth AP (2005). Evaluation of (Q)SARs for the Prediction of Eye Irritation/Corrosion Potential -Physicochemical Exclusion Rules. EUR 21897 EN. Available for download from ECB (http://ecb.jrc.it/QSAR) as of 2008-04-13.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Polymers (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.