File No: LTD/1503

August 2011

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sta-Lok

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 Sustainability, Environment, Water, Population and Communities.

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 Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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:	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

TABLE OF CONTENTS

FULL PUBLIC REPORT

Sta-Lok

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Tate & Lyle (ABN 28 121 048 262)
Level 2, 39 Park Street,
South Melbourne, VIC 3205

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da

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, analytical data, polymer constituents, residual monomers, and identity of analogue.

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 (n-octanol/water), and adsorption/desorption.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (1994)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sta-Lok (product containing the notified polymer around 100%)

MOLECULAR WEIGHT
Mn >10,000 Da

ANALYTICAL DATA
Reference IR spectra was provided.

3. COMPOSITION

DEGREE OF PURITY 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

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

ADDITIVES/ADJUVANTS
None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
None

DEGRADATION PRODUCTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: White, powdery substance

Property	Value	Data Source/Justification
Melting Point	Not determined	The analogue chemical decomposes around 200°C*.
Boiling Point	Not determined	The notified polymer is a powder.
Density	1500 kg/m^3	Analogue data*
Vapour Pressure	Not determined	Approximately zero for analogue chemical*.
Water Solubility	0.62% - 1.15% at 23°C	Measured. A full test report was not provided. However, the notified polymer is expected to be water dispersible, based on its structure and use pattern.
Hydrolysis as a Function of pH	Not determined	The notified polymer is not expected to hydrolyse under environmental conditions.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to partition from octanol to water, based on its high water solubility.
Adsorption/Desorption	Not determined	Based on its net positive charge, the notified polymer is expected to sorb strongly to soil and sediment.
Dissociation Constant	Not determined	The notified polymer is a salt and is expected to be ionised at environmental pH (4 – 9).
Particle Size	0.1-0.8 µm	Estimated
Flash Point	Not determined	The notified polymer is a powder.
Flammability	Can burn if strongly heated. May ignite on hot surfaces.	Analogue data*
Autoignition Temperature	May self heat. Static ignition hazard. May undergo spontaneous combustion when stored wet in large quantities.	Analogue data*
Explosive Properties	Powered material may form explosive dust-air mixture, which can be ignited by a spark or flame.	Analogue data*

*Physico-chemical properties were not submitted for the notified polymer. Therefore, analogue data were used for the physico-chemical properties.

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

The notified polymer is considered stable and is incompatible with oxidizing agents.

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 do 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 CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will be imported neat (> 99% concentration) as a dry white powder.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	27	27	27	27	27

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Hercules Chemicals Australia

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 23 or 46 kg multiwall paper bags and/or 907 kg bulk bags.

USE
The notified polymer will be used as a wet-end additive for the production of paper and paperboard at a concentration of < 3%.

OPERATION DESCRIPTION
Reformulation of notified polymer
The notified polymer will be imported neat as a dry powder at > 99% concentration and transported to customer sites. At customer sites, the notified polymer will be reformulated into wax emulsion products. The wax emulsion products will contain the notified polymer at < 3%.

During reformulation the notified polymer will be added directly to mixing tanks from the imported bags via a manway and mixed with water and other ingredients to form a wax emulsion. The tanks will be connected to a dust extraction unit and will be located in a well ventilated area. The tanks will be closed during mixing. The finished wax emulsion will be pumped from the mixing tanks and stored in dedicated storage tanks. The wax emulsion will be sampled and adjusted to specification.

Manufacturing of paper and paperboards
The wax emulsion containing the notified polymer at < 3% will be used in the manufacturing of paper and paperboard products.

The above formulated wax emulsion will be added to the paper stock to improve drainage, strength and retention on the paper machine. In the paper machine, the solution containing the pulp, notified polymer (at <3% concentration) and other chemical additives will be mixed, refined, sieved, pressed, dried, sized and spooled onto rollers to produce finished paper and paperboard products. Most paper machines operate by utilising a closed system where most of the processed water is recirculated and reused. The expected concentration of the notified polymer present in the finished paper and paperboard products will be < 0.1%.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
Importation, transport and storage
Worker exposure to the notified polymer during importation, transport and storage is not expected, except in the unlikely event of an accident where its packaging may be breached.

Reformulation of notified polymer
Dermal, ocular and inhalation (dusts) exposure to the notified polymer is possible during reformulation of the neat notified polymer (> 99% concentration, as a dry powder) into products containing < 3% notified polymer. However, exposure is expected to be limited due to the use of a closed tank, a dust extraction unit on the mixing tank, location of the tank in a well ventilated area, and personal protective equipment (PPE) such as dust masks/respirators, eye protection, impervious gloves and coveralls.

Manufacturing of paper and paperboards
Workers exposure is also possible during manufacturing of paper and paperboards from wax emulsion

containing the notified polymer at < 3%. However, exposure is expected to be minimal due to the low concentration (< 3%) of the notified polymer used in this process and the expected closed system employed by most paper machines.

End-use
Office workers will make dermal contact with the dried paper containing notified polymer at <0.1% concentration. Exposure to the notified polymer is expected to be negligible because the notified polymer is present at low concentrations in the paper (< 0.1%), 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 general public. The potential for general public exposure to the notified polymer during transport, reformulation and manufacturing of paper is likely to be negligible. The general public will make dermal contact with the finished paper and paper board products containing the notified polymer at < 0.1%. However, the notified polymer is expected to be irreversibly bound to the paper matrix during manufacturing process and will not be bioavailable for exposure. Thus, exposure to the general public, when handling products containing the notified polymer, is not considered to be unreasonable.

6.2. Human health effects assessment

No toxicity data were submitted for the notified polymer.

Based on the high molecular weight (>10,000 Da) of the notified polymer and absence of low molecular species (MW < 1000 Da), the notified polymer is not expected to cross biological membranes, hence systemic toxicity is not expected.

The notified polymer does not contain any structural alerts for toxicity hence it is not expected to have irritation, sensitisation or genotoxic potential.

Health hazard classification
Based on the provided data the notified polymer is not 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
No toxicity data were provided for the notified polymer. However, based on the high molecular weight and in the absence of structural alerts, the notified polymer is not expected to pose a hazard to human health.

The notified polymer as imported in the powdered form is estimated to be mainly composed of particles in the respirable range (< 10 μm). The notified polymer is water soluble and therefore if inhaled at low levels is likely to be cleared from the upper respiratory tract readily through mucociliary action. Small proportions of the notified polymer may reach the lower respiratory tract, but it should still be readily cleared from the lungs unless high levels are inhaled. When high concentrations of the notified polymer are inhaled, it is likely to be cleared from the lungs, but this may be slower and temporary respiratory impairment is possible. The expected use of dust masks and local exhaust ventilation should reduce inhalation exposure levels and hence lower the risk of temporary lung overloading.

Given the expected low hazardous nature of the notified polymer and proposed use of respiratory protection and engineering controls (i.e. local exhaust ventilation) to minimise inhalation of dusts, the risk to workers using the notified polymer is not considered to be unreasonable.

6.3.2. Public health
When used in the proposed manner, exposure to the notified polymer is expected to be negligible therefore the risk to public health from the notified polymer is not considered unreasonable.

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 as a neat powder for use as a wet-end additive during the production of paper and paperboard. No significant release of the notified polymer to the environment is expected from transport and storage processes. In the case of an accidental spill, the notified polymer is expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE
At industrial sites, after a series of reformulation steps, the notified polymer will be incorporated into a wax emulsion at a concentration of < 3%. The wax emulsion will be used at the wet-end of the paper manufacturing process and will be used in paper making machines that produce finished paper and paperboard products. The notifier indicated that 75% of the notified polymer will adsorb onto the paper fibre during the application processes. The remaining notified polymer (25%) will enter the customer's on-site wastewater treatment facilities consisting of a primary clarifier, aerobic treatment ponds, secondary clarifier and settling ponds. This treatment system is expected to remove > 98% of solids before release to surface waters.

RELEASE OF CHEMICAL FROM DISPOSAL
It is assumed that 50% of the paper to which the notified polymer is applied will go to landfill and the remainder will enter the paper recycling stream.

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 is not likely to bioaccumulate.

The majority of notified polymer is expected to be disposed of to landfill as a component of paper products and as sludge collected from paper recycling processes. A significant proportion of the notified polymer is anticipated to be released to the aquatic environment due to the recycling of paper products containing the notified polymer. 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 recycling 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).

Additionally, some of the notified polymer may be discharged to receiving waters from the on-site water treatment plants of paper mills. In this scenario a high proportion of the notified polymer in receiving surface waters and treated waters is expected to be removed from the water column by sorption to sediments and organic carbon due to its net cationic charge and high molecular weight (Boethling and Nabholz, 1997).

In either landfill or water, the notified polymer is expected to undergo degradation by biotic and abiotic processes, eventually forming water, oxides of carbon and nitrogen and inorganic salts.

7.1.3 Predicted Environmental Concentration (PEC)

Paper Manufacture
It is assumed under a worst case scenario that the notified polymer will be used at a single paper mill. At the paper mill, up to 25% of notified polymer is expected to enter the on-site wastewater treatment facilities. The treatment facilities consisting of a primary clarifier, aerobic treatment ponds, secondary clarifier and settling ponds was reported by the notifier to remove > 98% of solids. The product containing the notified polymer (at a

concentration of < 3%) will be used at 75 kg/hr, hence the notified polymer will enter the clarification system at a rate of (75 kg × 3% × 25%) / hr = 0.5625 kg/hr. The waste stream enters the clarification system at 250,000 L/hr, hence the notified polymer will enter the clarification system at a concentration of 2.25 mg/L. Based on the 98% removal rate, the notified polymer will therefore be released to receiving waters at a maximum concentration of (2% × 2.25 mg/L) = 45 µg/L. This is an upper limit riverine predicted environmental concentration (PEC_{river}) since the notified polymer is expected to be diluted in receiving waters and, based on its net cationic charge, be removed from the water via sorption to sediment and organic matter.

Paper Recycling

Up to 37.5% (10,125 kg per annum) of the imported quantity of notified polymer that is applied to paper at the paper mill could potentially enter the paper recycling stream in Australia (i.e. 75% applied to paper × 50% of paper recycled × 27,000 kg). The typical concentrations of the notified polymer in surface waters resulting from paper recycling can be calculated using a worst case continental model in which it is assumed that 90% of the notified polymer entering waste water treatment plants is removed from the influents (Boethling and Nabholz, 1997). It was assumed the release of the notified polymer will occur over 260 days per annum into the total Australian effluent volume. This corresponds to release from recycling processes only on working days, based on a 5 day work week.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	27,000	kg/year
Proportion expected to be released to sewer	37.5%	
Annual quantity of chemical released to sewer	10,125	kg/year
Days per year where release occurs	260	days/year
Daily chemical release	38.94	kg/day
Water use	200	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:	0.92	µg/L
PEC - Ocean:	0.092	µg/L

Partitioning to biosolids in sewage treatment plants (STPs) Australia-wide may result in an average biosolids concentration of 41.407 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 0.276 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 1.38 mg/kg and 2.76 mg/kg, respectively.

Based on the above calculations, the maximum PEC for the notified polymer in surface water is 45.92 µg/L (= 45 + 0.92) for river waters and 4.592 µg/L (= 45/10 + 0.092) for ocean waters receiving combined effluents from paper recycling and paper manufacture.

7.2. Environmental effects assessment

Ecotoxicological endpoints for the notified polymer were calculated based on quantitative structure activity relationship (QSAR) equations for estimating the toxicity of polycationic polymers to daphnids (Boethling and Nabholz, 1997). QSAR equations were not available for fish and algal endpoints. The endpoints are summarised in the table below.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	LC50 (48 h) = 397 mg/L	Not harmful to aquatic inverterbrates
Daphnia Toxicity	ChV* = 28.32 mg/L	Not harmful to aquatic invertebrates with long lasting effects

*Chronic Value = (NOEC × LOEC)^{½}. Determined in this case by an acute to chronic ratio (ACR) of 14.

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). However, an analogue with a comparable cationic charge density and similar backbone type to the notified polymer had very low toxicity to fish and daphnids (L(E)C50s > 1000 mg/L). Hence on a weight of evidence approach, the notified polymer is not expected to be acutely harmful to aquatic organisms in environmental waters.

7.2.1 Predicted No-Effect Concentration

The most sensitive endpoint from the ecotoxicity calculations on the notified polymer is the chronic value for daphnids and this was selected for the calculation of the Predicted No-Effect Concentration (PNEC) below. A conservative assessment factor of 500 was used as although a chronic end-point is available the QSAR did not derive a NOEC and endpoints are only available for one trophic level.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ChV	28.32	mg/L
Assessment Factor	500	
PNEC:	57	µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q – River	< 45.9	57	< 0.81
Q – Ocean	< 0.459	57	< 0.081

The Risk Quotient (Q = PEC/PNEC) has been calculated to be < 1 for both river and ocean discharges of industrial effluents containing the notified polymer and releases from paper recycling. The risk quotient indicated a relatively narrow safety margin as a result of the potential release of the notifier polymer to surface waters during paper manufacturing processes. However, the calculations represent conservative estimates for the release rates of the notified polymer from paper manufacture and paper recycling facilities that likely overestimate the concentration of the polymer in aquatic systems. The absence of any significant expected ecotoxicological effects combined with the relatively low concentration of the polymer occurring in surface waters, even at the theoretical worst case levels, indicates that there is no unreasonable risk to the aquatic environment from the intended use of the notified polymer as an additive in paper manufacture.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the provided data the notified polymer cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(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 PEC/PNEC ratio and 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

- Employers should implement the following engineering controls to minimise occupational exposure to dusts of the notified polymer:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure:
  - Avoid inhalation of dusts

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to dusts of the notified polymer:
  - Respiratory protection (i.e. dust masks)

  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 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
  - there is a change in the waste water treatment procedures at the paper mills;

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from an additive in paper and paper board production, or is likely to change significantly;

- the amount of polymer being introduced has increased from 27 tonnes per annum, 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.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility 0.62% – 1.15% at 23°C

Method	In-house method
Remarks	A full test report was not provided. The procedure involved mixing the sample with water, centrifuging the mixture, evaporating an aliquot of the supernatant and calculating the residue as solubles.
Test Facility	Tate & Lyle (2010)

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.

Tate & Lyle (2010) Tate & Lyle Analytical Department, Decatur, Illinois, USA (Summary of an unpublished report provided notifier).

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.