File No: LTD/1396

February 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

PS100 Polymer

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, 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

PS100 Polymer

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Akzo Nobel Pty Ltd (ABN 59 000 119 424)
115 Hyde Road
YERONGA QLD 4104

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, CAS number, Molecular and Structural formulae, Molecular weight, Spectral data, Methods of detection and determination, Purity, Impurities, Introduction volume, Use details and Identity of manufacturers.

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
Canada, China, EU, Japan, Korea and USA.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
PS100 polymer
RC3817 Incacryl PS 100 (containing < 35% notified polymer)
Interfine 1080 (containing < 25% notified polymer)

MOLECULAR WEIGHT
Mn > 1000 Da.

ANALYTICAL DATA
Reference NMR, IR, GC and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 98% (imported in ≤ 30% Xylene)

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
There are hazardous impurities present, however these are all below the cut-off concentration for classification as hazardous.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20ºC AND 101.3 kPa (for PS100 containing < 70% notified polymer in xylenes): Clear, colourless, slightly viscous liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20°C	Measured
Density	1,030 kg/m^3 at 20°C	Measured

Vapour Pressure	1.1 x 10^{-5} kPa at 25 ^{o}C	Measured
Water Solubility	1.6 x 10^{-4} g/L at 20^{o}C	Measured
Hydrolysis as a Function of pH	Very slow (essentially stable).	Estimated
Partition Coefficient (n-octanol/water)	log P_{ow} > 6.5 at 20^{o}C	Measured
Adsorption/Desorption	log K_{oc} > 5.6 at 30°C	Measured
Dissociation Constant	pKa = 9.5	Estimated
Flash Point	32 ^{o}C at 101.325 kPa	Measured flashpoint likely due to xylenes
Autoignition Temperature	> 400^{o}C	Measured
Explosive Properties	Not predicted to be explosive	Estimated based on chemical structure
Oxidising Properties	Not predicted to be an oxidising agent	Estimated based on chemical structure

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

Reactivity
The notified polymer is expected to be stable under most normal conditions. However, the polymer contains a reactive functional group that reacts with water to generate a flammable gas.

Dangerous Goods classification
Based on the available data the notified polymer as imported in PS100 Polymer and Incacryl PS100 Polymer RC3817 in xylenes is classified as follows according to the Australian Dangerous Goods Code (FORS, 1998):
Class 3 – Flammable Liquids

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. Initially it will be imported into Australia at a concentration < 25% as part of a formulated paint such as Interfine 1080 ready for direct supply to customers. In the future it is possible that the notified polymer will be imported into Australia as part of a resin mixture (RC3817 Inacryl PS100) for blending into the final paint product.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.5	< 10	< 10	< 10	< 10

PORT OF ENTRY
Brisbane

TRANSPORTATION AND PACKAGING
The finished paint (Interfine 1080) containing the notified polymer at < 25% will be imported by sea in cartons of 20 L cylindrical lined open-top pails or 5 L cylindrical cans. It will be taken by road to a warehouse before distribution to customers by road. In future, the notified polymer at < 35% may be imported in a resin solution (RC3817 Inacryl PS100) in 200 L sealed, lined drums.

USE
The notified polymer will be used as a component of industrial heavy-duty protective paint products.

OPERATION DESCRIPTION
Formulation of RC3817 Inacryl PS100 into paint products
RC3817 Inacryl PS100 (containing < 35% notified polymer) will be transferred manually from the import containers to a steel pan where it will be blended with other paint components. The mixture will then be passed through a bead mill into another steel pan before transfer to product cans.

End use of paint products

Paint products containing the notified polymer (< 25%) will be applied to metal surfaces in an industrial setting by professionals. Application will usually be by spray, with one worker using a spray gun and another ensuring a constant supply of paint to the spray equipment. Application will usually occur outside, although painting of smaller articles may occur inside, either in large sheds or in spray booths. Occasionally, paints will be applied by roller or brush.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and warehousing	10	minimal	60
Unloading	1	minimal	2
Paint formulation – charging	≤ 2	1	40
Paint formulation – mixing, milling	≤ 4	6	40
Paint formulation – filling	≤ 2	6	40
Paint formulation – cleaning/disposal	≤ 3	1	40
Spray application	6	6	75
Spray application (refilling)	6	6	75

EXPOSURE DETAILS

Formulation into paint products

Occupational exposure to the notified polymer is expected to be greatest for workers involved in paint reformulation as they will be handling the imported resin containing the notified polymer at < 35%.

During paint formulation, workers may be exposed to the chemical via dermal and ocular exposure to drips, spills and splashes during manual pouring into steel pans, during milling using a bead mill, and during filling of paint product containers. However, exposure will be minimised by workers wearing personal protective equipment (PPE) such as coveralls, safety goggles, and impervious gloves.

The potential for inhalation exposure to aerosols generated during the blending and milling processes is expected to be minimal, based on the notifier's description of the process, which includes covered pans and exhaust ventilation, as well as respirators as required.

End use of paint products

Inhalation will be the primary route of potential exposure during application of paints containing the notified polymer (< 25%). The spray application will occur either with natural ventilation (outside or in large shed) or in a spray booth. EASE modelling of inhalation exposure during spray application of paints containing the notified polymer (< 25%) without exhaust ventilation or respiratory protection, estimate the level of exposure to be 500 – 1000 ppm assuming that the use pattern is wide dispersive use, there is direct handling, and the vapour pressure of the substance is $1x10^{-5}$ kPa. The use of a respirator and/or local exhaust ventilation would minimise exposure.

Dermal and ocular exposure to spills, drips and splashes of the paint is also possible during spray application, although more likely during roller and brush application. PPE, such as coveralls, safety goggles and impervious gloves, are expected to be worn to minimise exposure.

6.1.2. Public exposure

The notified polymer is intended for industrial use only and therefore public exposure is not anticipated during application. The public may come into contact to surfaces coated with paints containing the notified polymer. However, the notified polymer will be cured into an inert matrix and hence will not be bioavailable.

6.2. Human health effects assessment

The results from a toxicological investigation conducted on the notified polymer are summarised in the table below. Details of the study can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Mutagenicity – bacterial reverse mutation	non mutagenic

The notified polymer is not expected to be significantly absorbed across biological membranes due to its high number-average molecular weight (> 1000 Da.), low water solubility (< 1 mg/L) and high log P_{OW} value (> 6).

The notified polymer was found to be non-mutagenic in a bacterial reverse mutation (Ames) test using *S. typhimurium* strains: TA1535, TA1537, TA98 and TA100 and *E. coli* WP2uvrA$^-$ in the absence and presence of metabolic activation at concentrations up to 5000 µg/plate (Safepharm Laboratories Ltd 2008b). No cytotoxicity or precipitation was observed at any concentration during the test. The test was conducted according to OECD TG 471.

The notified polymer contains functional groups that may be of concern for inhalation toxicity (US EPA 2002). The degree of concern for these types of polymers depends on the relative abundance of lower molecular weight species, but there is no molecular weight threshold above which there would be no concern (US EPA, 2002). The percentage of low molecular weight species in the notified polymer is less than 10%, indicating a lower degree of concern. However, the potential for lung effects after repeated exposure cannot be ruled out.

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The primary concern for workers handling the notified polymer is the potential for lung effects following inhalation of aerosols during spray application. The notified polymer will be imported diluted with solvents either in a resin (< 35%) or in paint products (< 25%). These resin and the paint products contain solvents at concentrations exceeding hazard classification cut-off limits. The measures taken to minimise dermal, ocular and inhalation exposure to the solvents in the resin and paints will also reduce exposure to the notified polymer. If appropriate ventilation and respiratory protection are used when spraying paint containing the notified polymer, the risk of adverse effects is not expected to be unacceptable.

6.3.2. Public health
The public are not expected to be exposed to the notified polymer during application and once dried it is not expected to be available to cause exposure. Therefore, the risk of the notified polymer to the health of the public is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1 Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will initially be imported in a finished paint. Environmental exposure from local formulation, should it occur, is expected to be low as paint formulation is generally a simple blending process that is highly controlled. If paint is spilt or remains as drum residues, the notified polymer will be immobilised in an inert solid when the paint dries.

RELEASE OF CHEMICAL FROM USE
Solid waste (dried paint) will not contain the notified polymer as this will have reacted to become part of the complex matrix which makes up the paint film.

Solid waste (dried paint) will be disposed of to landfill; at this stage the notified polymer would be immobile

when bound in the cured paint matrix.

There is a possibility of release of the notified polymer from drips of paint falling to the ground. This will be minimal as the paint will be applied by professionals, who should tarp accordingly to prevent drips and to catch overspray. Drips will quickly dry, sealing the polymer into the paint matrix and making it unavailable to water or soil. Dry spray is recovered and will be disposed of to landfill in accordance with local regulations.

These controls and the fact that the polymer is unlikely to be released from dry paint will mean that loss of the notified polymer to surface waters will not occur.

RELEASE OF CHEMICAL FROM DISPOSAL
Waste generated will mainly be in the form of dry overspray and dried paint left in tins. In both cases any notified polymer left in the dried paint will be minimal due to it reacting to become part of the complex matrix, so what is left will be trapped within the dry paint.

Waste paint will generally be allowed to cure, trapping any residual notified polymer within the paint film. Depending on the amount of paint left in the tin it may be possible for these to be recycled. Alternatively it will be disposed of to landfill.

7.1.2 Environmental fate

No environmental fate data were submitted. The notified polymer is not expected to be readily biodegradable or bioaccumulate, based on its structure. It will have very low mobility in the environment, particularly when incorporated in dried paint matrices.

7.1.3 Predicted Environmental Concentration (PEC)

It is neither necessary nor meaningful to estimate the PEC as the notified polymer is not expected to enter aquatic environments when used as intended. If spilt to water, the notified polymer would be expected to precipitate as an inert solid and degrade slowly in sediment.

7.2 Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer lacks significant ionic functionality and is of low concern to the aquatic environment.

7.2.1 Predicted No-Effect Concentration

The PNEC cannot be estimated as the notified polymer has not been tested for aquatic toxicity. Based on its structure, the notified polymer is expected to have very low water solubility, and to be nontoxic to aquatic life at concentrations below the solubility limit.

7.3 Environmental risk assessment

The notified polymer is not expected to enter aquatic environments, and is of low concern to the aquatic environment based on its structure. Therefore, the notified polymer is not considered to pose a risk to the environment.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is inapplicable as no aquatic toxicity data are available. The notified polymer is not expected to be harmful to aquatic life, based on its structure.

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 considered to not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the chemical structure and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced as PS100 Polymer, and in the products RC3817 Inacryl PS 100 and Interfine 1080:
  - *Local exhaust ventilation where aerosol generating activities involving the notified polymer are carried out.*

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced as PS100 Polymer, and in the products RC3817 Inacryl PS 100 and Interfine 1080:
  - *Organic vapour respirator.*

- A copy of the MSDS should be easily accessible to employees.

If products and mixtures containing the notified chemical 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 chemical should be disposed of by landfill.

Storage

- The following precautions should be taken by Akzo Nobel Pty Ltd regarding storage of the notified polymer:
  - *No smoking or naked flame in storage areas.*

Emergency procedures

- Spills or accidental release of the notified chemical 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 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 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 chemical has changed from component of paint products, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- 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.

Material Safety Data Sheet
The MSDS of the notified polymer and products containing 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

Melting Point/Freezing Point < -20°C

Method	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Test Facility	Safepharm Laboratories Ltd (2008a)

Density 1,030 kg/m^3 at 20°C

Method	OECD TG 109 Density of Liquids and Solids. EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Pycnometer method
Test Facility	Safepharm Laboratories Ltd (2008a)

Vapour Pressure 1.1x10^{-5} kPa at 25°C

Method	OECD TG 104 Vapour Pressure. EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	Measured with Vapour pressure balance. The xylene solvent was removed by vacuum pump prior to the measurements.
Test Facility	Safepharm Laboratories Ltd (2008a)

Water Solubility 1.64 x 10^{-4} g/L at 20°C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. The guideline recommends use of the column elution method where solubility is less than 10 mg/L, but experience had shown that materials of this nature tend to cause the beads to adhere together and clog the column. HPLC analysis of the saturated aqueous solution produced a different peak profile to the analytical standard, reflecting preferential solubilisation of certain components.
Test Facility	Safepharm Laboratories Ltd (2008a)

Hydrolysis as a Function of pH

Method	The test was not conducted because of the low solubility of the notified polymer and the lack of suitable analytical methodology.
Remarks	The notified polymer is expected to be stable to hydrolysis, although it contains some potentially hydrolysable functionality. The hydrolytic half-life was estimated as years to centuries using specialist software.
Test Facility	Safepharm Laboratories Ltd (2008a)

Partition Coefficient (n-octanol/water) log Pow > 6.5 at 20°C

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method. The test substance was less mobile than the reference standard DDT, and could only be removed from the column after significantly modifying the mobile phase. The result should be treated with caution given the limitations of this parameter in relation to polymers. The log P_{ow} can be estimated as > 1.29 based on the solubilities in water (< 7.7 mg/L) and octanol (0.149 g/L).
Test Facility	Safepharm Laboratories Ltd (2008a)

Adsorption/Desorption – screening test log K_{oc} > 5.6 at 30°C

Method	OECD TG 121 Adsorption - Desorption HPLC Screening Method.

Remarks	It was considered possible that the notified polymer was partially ionised, given the predicted dissociation constant of 9.54. However, no differences in retention times were observed when the pH of the mobile phase was adjusted (pH 3, 7 and 9). The test substance was less mobile than the reference standard DDT. The result should be treated with caution given the limitations of this parameter in relation to polymers.
Test Facility	Safepharm Laboratories Ltd (2008a)

Dissociation Constant pKa = 9.54

Remarks	Testing was not conducted because of the low solubility of the notified polymer and the lack of suitable analytical methodology. The polymer contains no readily dissociable functionality. Specialist estimation software was used to predict the above value.
Test Facility	Safepharm Laboratories Ltd (2008a)

Flash Point 32°C at 101.325 kPa

Method	EC Directive 92/69/EEC A.9 Flash Point.
Remarks	Flash point obtained considered to be due to the xylene content rather than the notified polymer.
Test Facility	Safepharm Laboratories Ltd (2008a)

Autoignition Temperature > 400°C

Method	EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).
Test Facility	Safepharm Laboratories Ltd (2008a)

Explosive Properties

Method	EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks	Not expected to be explosive based on the chemical structure.
Test Facility	Safepharm Laboratories Ltd (2008a)

Oxidizing Properties

Method	EC Directive 92/69/EEC A.17 Oxidizing Properties (Solids).
Remarks	Not expected to be oxidizing based on the chemical structure.
Test Facility	Safepharm Laboratories Ltd (2008a)

BIBLIOGRAPHY

EC (2003) EC (2003) Technical Guidance Document on Risk Assessment, Part I. Institute for Health and Consumer Protection, European Chemicals Bureau, Joint Research Centre, European Commission.

FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service

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.

Safepharm Laboratories Ltd (2008a) PS 100 Polymer: Determination of General Physico-Chemical Properties. SPL Project Number: 2112/0029. Safepharm Laboratories Ltd, Derbyshire, England (Unpublished report provided by notifier).

Safepharm Laboratories (2008b) PS 100 Polymer: Reverse Mutation Assay "Ames Test" using *Salmonella Typhimurium* and *Escherichia Coli.* Project Number: 2112/0031. Safepharm Laboratories Ltd, Derbyshire, England (Unpublished report provided by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.

US EPA (2002) TSCA New Chemicals Program Chemical Categories, Office of Pollution Prevention and Toxics, US EPA, p.16. Available 3 December 2008 [online]: http://www.epa.gov/opptintr/newchems/pubs/cat02.pdf