File No: PLC/376

8 September 2003

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Solsperse 54000

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Solsperse 54000

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Orica Australia Pty Ltd (ABN 004 117 828)
1 Nicholson Street
Melbourne VIC 3000

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
CAS Number
Molecular Formula
Structural Formula
Means of Identification
Number Average Molecular Weight
Weight-average Molecular Weight
Weight Percentage of polymer species with MW<1000 and MW<500
Polymer Constituents
Residual Monomers and Impurities

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Particle Size Distribution
Flammability Limits
Auto ignition Temperature

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA, Canada, and Korea (all current).

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Substance HPA 22/1

MARKETING NAME(S)
Solsperse 54000

3. COMPOSITION

PLC CRITERIA JUSTIFICATION

Functional Group	Category	Equivalent Weight (FGEW)
Ether	Not considered a Reactive Functional Group	

Charge Density	The notified polymer has low charge density.
Elemental Criteria	The notified polymer contains only approved elements.
Degradability	The notified polymer is not biodegradable.
Water Absorbing	The notified polymer is not a water-absorbing polymer.

Residual Monomers	All residual monomers are below the relevant cut-off.
Hazard Category	The notified polymer is not classified as a hazardous substance.

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

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

USE

Solsperse 54000 is a polymeric dispersant used in alcohol-based flexographic packaging inks.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	Dark amber liquid
Melting Point/Glass Transition Temp	<25ºC
Density	1090 kg/m^3 at 20ºC
Water Solubility	The maximum extracted in a range of pHs after 14 days at 40ºC was 140 mg/L at pH 4-9. At pH 4 this was mainly low MW species while at pH 9 more high MW species were extracted (Avecia, 2002).
Flash Point	230-235ºC
Explosive Properties	No explosive properties expected, based on structure.
Degradation Products	No degradation expected under normal use conditions
Loss of monomers, other reactants, additives impurities	None
Hydrolysis as a Function of pH	The notified polymer does not contain any groups that are capable of hydrolysis. However, the stability of the notified polymer was determined at pH 1.2, 4, 7 and 9 (Avecia 2002). The notified polymer (0.13-0.16 g) was added to centrifuge tubes and to these was added the appropriate buffer (40 mL). The resulting suspensions were shaken for up to 2 weeks at 40ºC. After a period of equilibration the samples were filtered, freeze dried and the resulting residue weighed. The mean recoveries at all pHs were less than 4% indicating that the notified polymer is not readily soluble at these pHs.
Partition Coefficient (n-octanol/water)	The low water solubility of the notified polymer and its likely hydrophobic nature are indicative of partitioning into the octanol phase.
Adsorption/Desorption	The notified polymer is expected to have a high affinity for soil and sediment and be immobile in the environment due to its low water solubility.
Dissociation Constant	The notified polymer contains a terminal alcohol group which is not expected to dissociate in the environmental pH range of 4-9.

7. HUMAN HEALTH IMPLICATIONS

7.1 Toxicology

An acute oral study in rat was submitted for the notified polymer (SafePharm, 2002) There were no deaths or signs of systemic toxicity observed during the study. The acute oral median lethal dose (LD50) of the notified polymer in rat was estimated to be greater than 2500 mg/kg bw.

Human Health Hazard Assessment
The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. Based on the oral toxicity study in rats, the notified polymer is of low acute oral toxicity.

7.2 Occupational Health

Occupational Exposure

INK FORMULATION PROCESS
Workers may become exposed when weighing and transferring the notified polymer into a mixing vessel for subsequent blending with pigments and other additives, and when drumming off ink formulations into 5L and 20L cans and pails. Workers may also be exposed to drips and spills when drumming off ink preparations and during cleaning of equipment. The loading operation is carried out under local exhaust ventilation. Personal protective equipment (PPE) includes coveralls, gloves and eye protection when carrying out the above activities.

Intermittent dermal exposure to the ink preparations is also possible when collecting samples for quality testing. Laboratory workers will wear laboratory coats, gloves and eye protection.

USE OF INK
Ink application will be applied using roller coating equipment for flexographic printing*. Dermal and ocular exposure to the ink preparation containing the notified polymer may occur when transferring ink into the ink trough with the highest exposure during cleaning and maintenance of printers. Printing workers will wear coveralls, gloves and eye protection when manually transferring ink into trough and during cleaning operations. Inks are filled under exhaust ventilation and coating equipment is fitted with a filtered exhaust system.

TRANSPORT AND STORAGE
During transport and storage, workers are unlikely to be exposed to the notified polymer except when the notified chemical is accidentally spilled such as in a transport accident.

Exposure Assessment
Dermal and ocular exposure can occur during certain formulation processes, and cleaning operations. However, exposure to significant amounts of the notified polymer is limited because of the engineering controls and personal protective equipment worn by workers.

After application and once dried, the ink containing the notified polymer is cured into an inert matrix and is hence unavailable to exposure.

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

* Flexographic printing involves a rotary in-line printing method that uses flexible resilient plates with raised images and fast-drying inks to create full-colour materials.

7.3 Public Health

Public Exposure

The public is unlikely to be exposed to the notified polymer during transport, storage, printing ink manufacture and printing ink application, except in the event of an accidental spill.

The public may make dermal contact the printed packaging material; however, the printing ink once dried and cured is firmly attached to the surface of the substrate and not available for exposure.

Exposure Assessment
The notified polymer is intended only for use in industry and will not be available to the public. Members of the public may have dermal contact with the dried ink from the packaging materials. Once the ink has dried, it is reported to be strongly bound to the substrate and is unlikely to be removed easily. Therefore, the potential for public exposure to the notified polymer is expected to be low.

8. ENVIRONMENTAL IMPLICATIONS

8.1 Ecotoxicology

Ecotoxicological Investigations
No toxicological data were submitted.

Environmental Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard

8.2 Environmental Contamination

Environmental Exposure
Manufacture:
During formulation of the ink, the notifier estimates that up to 200 kg per annum of notified polymer waste will be generated. This will be derived from the spills (50 kg per annum) and equipment cleaning (150 kg per annum). The notifier further indicates that empty import drums are expected to be rinsed and either recycled or disposed of to landfill. The resulting rinseate will be added to the ink formulation process. However, if this rinsing process does not occur, up to a further 300 kg per annum of the notified polymer may be disposed of to landfill.

It is anticipated that spills of the polymer solution and blended ink will be contained within the plant through the bunding systems in place. Spills will be collected and either recycled or removed by a licensed industrial waste contractor for incineration.

Use:
During use of the ink, the notifier estimates that up to 50 kg per annum of notified polymer waste will be generated from equipment cleaning. These wastes will either be recycled in production or collected a licensed industrial waste contractor for incineration. Virtually all of the notified chemical will eventually be released to the environment. Over 99.9% of the notified chemical will be bound to printed paper which will either be buried in landfills, incinerated or released from effluent deinking processes. Recycling of treated paper could result in release of a proportion of the notified chemical to the aquatic compartment. However, the environmental concentration is expected to be negligible. Where recycling does not occur the notified chemical will be disposed of to landfill where it is expected to remain bound to paper.

Exposure Assessment
The notified polymer is expected to have low water solubility and, as a result, will be immobile in both terrestrial and aquatic compartments. As a consequence, the notified polymer released to sewer or landfill is expected to rapidly associate with the soil matrix and sediments and slowly degrade through abiotic and biotic processes to water vapour and oxides of carbon. Liquid wastes resulting from the cleaning of formulation and application equipment will either be reused in subsequent formulations or incinerated. In landfill the notifier polymer will degrade via the processes described above.

The notified polymer is not expected to cross biological membranes due to its high molecular weight and low water solubility and is therefore not expected to bioaccumulate (Connell 1990).

9. RISK ASSESSMENT

9.1. Environment

Most of the notified polymer will interact with other ink components to form a stable polymer matrix and, once dry, is expected to be immobile and pose little risk to the environment.
The notified polymer is not likely to present a hazard to the environment when it is stored, transported and used in the proposed manner.

9.2 Occupational health and safety

The OHS risk presented by the notified polymer is expected to be low. The notified polymer may be present in formulations containing hazardous ingredients. If these formulations 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.

The control measures in place during ink formulation and end-use will ensure sufficient protection against the notified polymer. No specific reduction measures are necessary.

9.3 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 negligible because the notified polymer is present at low concentrations and will be bound within a matrix and unlikely to be bioavailable.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

There is Negligible Concern to public health when used as a polymeric dispersant used in alcohol –based flexographic packaging ink.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The notifier has provided MSDS in accordance with the schedule item B 12 of the *ICNA Act*. The accuracy of the information on the MSDS remains the responsibility of the applicant.

12. 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.

Environment

Disposal

- Wastes containing the notified polymer should be disposed of in landfill or by incineration.

Emergency procedures

- Spills/release of the notified polymer should be contained as described in the MSDS (ie. collect spilled material with an inert absorbent) and the resulting waste disposed of to an authorised landfill.

12.1. 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.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Avecia (2002) Substance HPA 22/1, Notification Data – Project No. 1275387: Avecia Research Centre, Manchester, UK (unpublished report submitted by Orica Australia Ltd).

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NOHSC (1994a) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

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