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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Solsperse 21000; Solsperse 3000

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Solsperse 21000; Solsperse 3000

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Orica Australia Pty Ltd of 1 Nicholson Street, Melbourne, Vic 3000

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:
Chemical name, CAS No., 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 and import volume.

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 and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
South Korea

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Substance HPA21K
Solsperse 21000
Solsperse 3000

MARKETING NAME(S)
Substance HPA21K

3. COMPOSITION

PURITY > 97% w/w approximately

PLC CRITERIA JUSTIFICATION

Functional Group	Category	Equivalent Weight (FGEW)
Carboxylic acid	Low Concern	N/A

Molecular Weight	The notified polymer meets the MW criteria
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

The notified polymer is a pigment dispersant used in plastics masterbatch and solvent based architectural paints. It is used at levels up to 5% by weight in plastics masterbatch and 1% by weight in paints.

The notifier indicates that customers include paint companies (~5-10) located throughout Australia, and plastic masterbatch processors (~3-5 companies) and masterbatch users (~20 processors). Approximately 20% of the notified polymer will be used in paint manufacture and 80% in plastics applications.

5. PROCESS INFORMATION

Paint Manufacture
The notified polymer, a light brown liquid/waxy paste, will be formulated into paints, mixed in 100 batches per year. Batch ingredients are either metered directly to the mixer or manually added from drums. Paints are stored and transported in 1 L, 4 L, 10 L and 20 L steel cans and pails, and transported by road and rail. The final concentration of the notified polymer in paints is up to 1% by weight.

Plastics Masterbatch Manufacture
The notified polymer will be mixed and blended with a polymer, pigments and fillers. The blend in then processed through an extruder into a polymer. Plastics masterbatches are stored and transported from formulation sites to customers in 1000 tonne 'bulki-box' containers, and transported by road or rail. The final concentration of the notified polymer in masterbatches is up to 5% by weight.

Plastics Article Manufacture
Most of the notified polymer will be incorporated into plastic articles. A wide range of articles may be manufactured using plastics masterbatch, and processes involved may include blow moulding, film casting and other thermoforming processes.

Architectural Paints
Paint containing the notified polymer will be used as a decorative paint in architectural applications. Professional and domestic painters may apply the paint with brushes or rollers and occasionally spray equipment.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa	The notified polymer is a brown viscous liquid or waxy paste
Melting Point	Approximately 10ºC
Density	0.9 at 20ºC
Vapour Pressure	Due to its high molecular weight the vapour pressure of the polymer is expected to be very low
Water Solubility	13 µg/mL (low MW variant); 24 µg/mL (high MW variant) (Avecia Limited, 2003a-b). Water solubility was measured gravimetrically using a stirring method at 25°C ±1°C in which excess amounts of test substances were added to water (in duplicate) and the solutions filtered after stirring overnight. The filtered solutions were then evaporated to dryness and the residues weighed to determine the solubility.
Particle Size	Not applicable
Partition Co-efficient	Log P est. = 4.6 (Solsperse 21000); log P est. = 4.3 (Solsperse 3000). For Solsperse 3000, the n-octanol solubility was determined using a visual method. The polymer was miscible in all proportions at ambient temperature.

	To calculate a partition co-efficient a nominal value of 50% (500000 µg/mL) was used (Avecia Limited, 2003a). For Solsperse 21000, solubility in octanol was measured gravimetrically using a stirring method at 25°C ± 1°C in which excess amounts of test substances were added to water (in duplicate) and the solutions filtered after stirring overnight. The filtered solutions were then evaporated to dryness and the residues weighed to determine the solubility (56.0% (w/v) at 25 °C ± 1°C (560000 µg/mL) (Avecia Limited, 2003b).
Flash Point	218°C
Degradation Products	No degradation under normal use
Loss of monomers, other reactants, additives impurities	No leaching of additives expected under normal use.

The polymer contains groups that may hydrolyse but shouldn't under ambient environmental conditions. Low water solubility and its neutral form should ensure partitioning to the organic phase and portion of soils and sediments. The notified polymer contains terminal CO_2H group that is expected to have typical acidity.

7. HUMAN HEALTH IMPLICATIONS

7.1 Toxicology

Toxicological Investigations
The following toxicological studies were submitted for Solsperse 21000:

Endpoint	*Assessment Conclusion*
Rat, acute oral	LD_{50} > 2000 mg/kg bw; low toxicity (1)
Rabbit, skin irritation – single 4-hour	Slight to moderately irritating (1)
Rabbit, skin irritation – repeated application	Moderate to severely irritating (1)
Rabbit, eye irritation	slightly irritating (1)
Mouse micronucleus test	Not clastogenic (2)
Reverse mutation assay (Ames test)	Non-mutagenic (3)

(1) = CTL (1988), (2) = CTL March (1990) and (3) = CTL (April 1990)

Skin irritation – single application (rabbit)

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2	1	1	3	4 days	0
Oedema	2.3	0.7	1.3	3	4 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

RESULTS Slight to moderately irritating to skin

Skin irritation – repeated application (rabbit)

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	3	2.7	3.7	4	< 8 days	0
Oedema	4	1.7	4	4	< 8 days	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

RESULTS Moderate to severely irritating to skin (after 4 application)

Eye irritation (rabbit)

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	0	0.33	1	1	72 hours	0
Conjunctiva: chemosis	0	0	0	0		0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

RESULTS Slightly irritating to conjunctivae. No effects on cornea or iris.

Health Hazard Assessment

The notified polymer meets the PLC criteria.

7.2 Occupational Health and Safety

Occupational Exposure
Paint manufacture:
Dermal exposure during opening and closing of container, adding and mixing in blender, filling containers. Eye contact to the notified polymer is also possible. Final concentration of the notified polymer is 1%

Plastic Masterbatch Manufacture:
Dermal exposure during opening and closing of container, adding and mixing in blender. Eye contact to the notified polymer is also possible. Final concentration of the notified polymer is 5%.

Plastic Article Manufacturer:
Dermal exposure to Masterbatch pellets during opening and closing of container, and moulding.

Architectural Paints:
Dermal exposure during opening and closing of container, and painting. Eye contact to the notified polymer is also possible. Inhalation exposure during spray application.

Exposure Assessment
Paint manufacture:
Exposure is likely to be low during formulation process because of engineering controls and use of personal protective equipment. However, incidental dermal exposure may occur during addition to the mixer.

Plastic Masterbatch Manufacture:
Exposure is likely to be low during formulation process because of engineering controls and use of personal protective equipment. However incidental dermal exposure may occur during addition to the blender.

Plastic Article Manufacture:
Exposure is likely to be low during article manufacture because notified polymer is bound within the matrix.

Architectural Paints:
Exposure is likely to be low since the concentration in paint is < 1%.

7.3 Public Health

Public Exposure

Exposure Assessment
Products containing the notified polymer are also for sale to the general public. Members of the public will make dermal contact and possibly accidental ocular contact with products containing the notified polymer. However, exposure will be low because the concentration of notified polymer is < 1%.

8. ENVIRONMENTAL IMPLICATIONS

8.1 Ecotoxicology

Ecotoxicological Investigations
The following toxicological studies were submitted:

Endpoint and Result	*Assessment Conclusion*
96 h LC50 Fish Acute Toxicity Test (Rainbow Trout)	Test invalid due to presence of undissolved material.
48 h EC50 *Daphnia* acute immobilisation test	>3.2 mg/L (above highest test concentration)

Aquatic ecotoxicity data were submitted by the notifier for rainbow trout (*Oncorhynchus mykiss*; Zeneca Limited, 1996a) and waterfleas (*Daphnia magna*; AstraZeneca UK Limited, 2002). A sewage sludge respiration inhibition test was also submitted (Zeneca Limited, 1996b).

A 96 h LC50 for rainbow trout of >180 mg/L (nominal) was determined at Brixham Environmental Laboratory, UK, using a static test; however, the notifier indicates that the test was invalid due to the presence of undissolved material on the water/air interface. The substance was not toxic up to the limit of water solubility.

48 h EC50 values for waterfleas exposed to Solsperse 21000 was >3.2 mg/L. The test was conducted at the Brixham Environmental Laboratory under static test conditions. The *Daphnia* test consisted of a solvent control and nominal test concentrations of 0.010, 0.032, 0.10, 0.32, 1.0 and 3.2 mg/L. The 32000 mg/L stock solution was prepared by dispersing 0.32 g of the test substance in 10 mL acetone. This solution was cloudy. The 3.2 mg/L test solution was prepared from this stock and the remaining test solutions were serial dilutions of the 3.2 mg/L solution with water. Five animals were tested per concentration and ten animals in the solvent control. Some immobility of test organisms occurred at lower test solutions but not at the two higher test concentrations, indicating random occurrences that should not affect test results.

Inhibition of activated sludge respiration was tested according to OECD Test Method 209 (OECD, 1992), incorporating ETAD Method 103. The test measured the inhibition of respiration over a 3 hour contact time period. The reference toxicant (3,5-dichlorophenol) indicated that the test organisms responded normally (ie. EC50 = 15 mg/L) therefore confirming the test's validity. Test substance containing the notified polymer at a nominal concentration of 100 mg/L resulted in <5% inhibition in respiration. An EC10 of >100 mg/L has been derived. The notified chemical is unlikely to adversely affect sewage sludge respiration processes.

8.2 Environmental Contamination

Exposure Assessment

RELEASE DURING TRANSPORTATION AND STORAGE

The notified polymer will be imported from the UK in 25 L and 205 L open head steel drums. It will be transported by road from the Port to a licensed chemical storage facility with engineering controls (ie. bunding) to safeguard against environmental release from spills. It will be distributed by road or rail to customers.

Environmental release is unlikely during importation, storage and transportation, and spillage during a transport accident the most likely reason for environmental release. Individual container capacity and container specifications would limit the extent of release.

RELEASE OF CHEMICAL AT SITE

Paint Manufacture

There is a potential for spillage of the notified polymer to occur during paint manufacture. The process is typically undertaken in a closed system, and spills are controlled by bunding within the plant. Mixers are fitted with exhaust ventilation to control emissions to workplace environment, and a regular maintenance program is pursued. As the chemical is not volatile, volatilisation to the atmosphere is expected to be limited. All quality control testing of paint involves spraying in approved booths subject to regular maintenance procedures. Paints are filled into containers under exhaust ventilation to capture volatiles.

At paint manufacturing sites (5-10), the notifier estimates about 40 kg of the notified polymer may be generated as waste as a result of minor spills (10 kg) and equipment cleaning (30 kg). This waste will be disposed of through licensed waste disposal contractors, and incineration is the most likely method of disposal.

Plastics Masterbatch Manufacture

Waste generated during masterbatch manufacture may arise from spillage. It is likely that polymer released into the masterbatch manufacturing facility will be captured through engineering controls. Spillage will be contained using absorbent material and disposed via a licensed waste disposal contractor to landfill. The notifier estimates <100 kg of notified chemical may be sent to landfill for disposal in this waste type. Dust and/or fume created during both plastics masterbatch manufacture and

manufacture of plastic articles is controlled by local exhaust ventilation. Waste polymer and plastics from masterbatch manufacture is likely to be consigned to licensed landfills.

Plastics Article Manufacture
Waste polymer and plastics masterbatch will be trapped in standard engineering controls in place. The waste is likely to be collected by licensed waste disposal contractors and most likely sent to landfill for disposal

RELEASE OF CHEMICAL FROM USE

Architectural Paints
During these applications, it is estimated that about 120 kg of notified polymer may be wasted as a result of container residues and equipment cleaning. Empty pails and cans are expected to contain residues of the notified chemical of up to 40 kg/annum. This waste will be sent to landfill for disposal. About 80 kg of notified chemical will be contained within wastes from washing of brushes and rollers in mineral turpentine. While the actual fate of the wastes generated by individual users in architectural situations is uncertain, a proportion of the notified chemical may potentially be discarded through domestic garbage collection, waste-paint collection facilities or tipped onto the ground.

Plastic Articles
Most (~80%) of the notified chemical will be use to manufacture plastic articles, and most articles will eventually be sent to landfills for disposal at the end of their useful life. Up to 8.8 tonnes of the notified chemical eventually disposed to landfills throughout Australia in used plastic articles over time

8.3 Disposal
The MSDS recommends that waste material be disposed of through a licensed waste contractor, and to avoid contaminating drains and waterways. The draft label makes no disposal recommendations, but refers the consumer to the MSDS and the Waste Management Authority. As such, it is expected that the majority of wastes generated during manufacture and industrial application will be disposed of through licensed waste contractors.

9. RISK ASSESSMENT

9.1. Environment

Up to 80% of the coatings containing the notified polymer will be applied to metal surfaces in industrial applications and the remaining 20% will be used as decorative paint in architectural applications. No environmental exposure is expected at end use once the paint has dried to form a hard and durable paint matrix. The notified polymer in plastic articles is fully encapsulated in the plastics matrix and as such is not likely to be released to the environment.

Up to 260 kg of waste may be generated during paint/plastics manufacturing and use each year as a result of incidental spills, equipment cleaning (brushes, rollers, spray equipment), and residues in containers. The majority of this waste will be sent to landfills for disposal. In landfill, the notified polymer in solid wastes is expected to be immobile, and eventually will degrade through biotic and abiotic processes, and consequently, should not pose a significant exposure hazard to the environment.

Spills of notified polymer to land are expected to bind to soil and are not expected to be mobile or affect groundwater due to very low water solubility. Spills of notified polymer to waters are not expected to dissolve, and may settle to sediment due to the lack of water solubility. However initially, the density of the notified polymer (0.9 at 20 °C) indicates that the substance will float on water. This was evident in aquatic toxicity tests using rainbow trout (Zeneca Limited, 1996a).

While no aquatic exposure is anticipated during normal usage of the coatings, there is a potential for aquatic exposure during architectural applications should individual household users improperly dispose of unwanted paint waste to sewer, if the notified polymer is able to pass into discharge effluent from sewage treatment plants. The amount entering the aquatic environment in this manner cannot be determined; however, it is expected to be small owing to the low concentration in the paint products and the paint is solvent-based, indicating that cleaning in water will not occur. In addition, the polymer is expected to bind to sediments and be retained in sewage sludge. Furthermore, the notified polymer

is not expected to cross biological membranes due to its high molecular weight. Paint manufacturers recommend that wastes generated during architectural applications (eg. brush/roller rinsate, waste paint) should be stored for municipal chemical waste collection days, and solid wastes sent to landfills.

9.2 Occupational health and safety

The notified polymer is irritating to skin, particularly after repeated exposure. It is also a slight eye irritant. Therefore there is risk of irritation when handling the polymer in its most concentrated form, that is, during weighing and addition to mixing vessels for formulation into paint and plastic masterbatch. Therefore, precautions such as enclosure and local exhaust ventilation must be taken to prevent skin and eye contact during these operations.

Once the polymer is formulated into paint, there is little risk of irritation due to the lower content of notified polymer (maximum 1%). Similarly, there is little risk of irritant effects when handling formulated masterbatch pellets as the polymer will be bound within the matrix.

During application of paints containing the notified polymer, the risk of irritation is low due to the low concentration of polymer in paint. However, precautions should be taken during spray application.

Worker exposure to the notified polymer during transport and storage is only possible in the event of an accidental spillage.

9.3 Public health

Domestic painters may apply the paint with brushes or rollers and occasionally spray equipment However, once applied, the notified polymer will form an inert film and will be no danger to the public. The notified polymer is of high molecular weight. Overall, public health risk from the introduction of the notified polymer into Australia is considered low.

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

10.2. Environmental risk assessment

The polymer is unlikely to pose an unacceptable 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 Low Concern to public health when used.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The notifier has provided MSDS for the notified polymer in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)]. The accuracy of the information on the MSDS remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- Use the following safety phrases for the notified polymer:
  - S24/25: Avoid skin and eye contact

CONTROL MEASURES
Occupational Health and Safety

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

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid spills during handling (Solsperse is slippery when wet)
  - Wear personal protective equipment when cleaning up spills

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Overalls, gloves, safety shoes/boots, and safety goggles

  - 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

- The notified polymer should be disposed of in accordance with the methods described in the Material Safety Data Sheet, including by licensed waste contractor and in accordance with local jurisdiction waste management guidance.

- Paint manufacturers recommend that wastes generated by paint users should be stored and disposed of at municipal chemical waste collection days. As much paint as possible from brushes, rollers and trays should be returned to the container for future use, and excess paint on brushes and rollers should be absorbed onto absorbent material such as old newspapers and allowed to dry and then disposed of with household waste. Unwanted paint should be kept and disposed of at municipal chemical waste collection days. Residual paint in empty containers should be allowed to dry out by leaving lids off.

Emergency procedures

- Spills/release of the notified polymer should be handled by containing and absorbing with sand and soil. The waste can then be collected and sealed in appropriately labelled drums for disposal.

. **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

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