

File No PLC/857

March 2010

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Solplus DP330

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:

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**Director
NICNAS**

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FULL PUBLIC REPORT**Solplus DP330****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Orica Australia Pty Ltd (ABN 99 004 117 828)
 1 Nicholson St
 MELBOURNE VIC 3000

NOTIFICATION CATEGORY

Polymer of Low Concern

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, Polymer Constituents, Residual Monomers/Impurities and Use Details.

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)

Nil

NOTIFICATION IN OTHER COUNTRIES

USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Solplus DP330 (notified polymer at 100% concentration)

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (Mn) > 1,000 Da

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION*Criterion**Criterion met*

Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	White powder
Melting Point/Glass Transition Temp	40°C
Density	1000 kg/m ³ at 15.6°C
Water Solubility	0.1– 0.2 ± 0.1 g/L at 20°C Water solubility was determined by following OECD TG 120 (pH 7, test samples in triplicate). The water soluble phase was separated from the insoluble phase by centrifugation followed by filtration. The analytical method was not reported.
Dissociation Constant	Contains a functional group that is expected to be ionised in the environmental pH range (4–9)
Particle Size	Not determined.
Reactivity	Stable under normal environmental conditions. The notified polymer contains hydrolysable functionalities, but hydrolysis is expected to be slow in the environmental pH range 4–9.
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10-30	10-30	10-30	10-30	10-30

Use

The notified polymer will be used as a dispersant for organic pigments in polyolefin thermoplastics.

The notified polymer will be imported at 100% concentration as a powder and transported to the notifier for formulation into plastic pellets. The notified polymer will be manually weighed and added to a hopper which leads to a mixer under exhaust ventilation. The notified polymer will be mixed with other thermoplastic ingredients and then fed directly into an extruder through a sealed tube. Once in the extruder, the mixture containing the notified polymer (<30%) will be melted, mixed and extruded through die holes to form small pellets. The pellets will be tested for quality control and packed into 25 kg laminated PVC bags for distribution to customers.

At the customer site, the pellets containing the notified polymer (<30%) will be fed manually or automatically into a hopper for injection moulding. The pellets will be heated along with other materials and fed into a mould for extrusion into the shape of the finished thermoplastic article containing the notified polymer at <1% concentration.

Mode of Introduction

The notified polymer will be imported in powder form at a concentration of 100% in 200 L drums.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and is therefore considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
1. Rat, acute oral	LD50 > 5000 mg/kg bw	yes	OECD TG 423
2. Rabbit, skin irritation	non-irritating	no	OECD TG 404
3. Rabbit, eye irritation	slightly irritating	yes	OECD TG 405

In an acute oral gavage toxicity study (OECD TG 423), effects observed were limited to hunched posture, piloerection and uncoordinated movements which had resolved by Day 2. The LD50 was established as >5000 mg/kg bw/day (NOTOX B.V., 2009a).

In a skin irritation study in rabbits (OECD TG 404), no signs of skin irritation were observed following 4-hour

application using a semi-occlusive dressing (NOTOX B.V., 2009b).

In an eye irritation studying rabbits (OECD TG 405), effects observed in the conjunctivae 1 hour after instillation included redness and/or chemosis and discharge. However, these effects had resolved by 24 hours in 1 animal and by 48 hours in the other 2 animals. The notified polymer was considered to be slightly irritating, based on these effects (NOTOX B.V., 2009c).

An inhalation toxicity study of the notified polymer was not conducted nor was its particle size determined. However, the particles of the notified polymer may be within the respirable range (<10 µm). Therefore, deposition may occur in the lungs, however, due to the relatively low molecular weight of the notified polymer (< 10,000 Da.), it is assumed to be cleared by normal lung clearance mechanisms.

Occupational Health and Safety Risk Assessment

Dermal and ocular exposure of workers to the notified polymer (at 100%) may occur when opening imported drums of the notified polymer, manual weighing and emptying into a hopper for blending. Exposure via the dermal and ocular routes may also occur during handling of pellets containing the notified polymer (<30%). However, workers are expected to wear personal protective equipment (PPE) such as safety glasses, gloves, dust mask and overalls to minimise the potential for dermal and ocular exposure.

Inhalation exposure to the notified polymer (at 100%) may occur during manual emptying of the imported product into a hopper for blending. Inhalation exposure to dusts of pellets containing the notified polymer (at <30%) may also occur when feeding the pellets into the hopper for extrusion into thermoplastic articles. However, exposure to workers involved in these processes is expected to be minimised by the implementation of local exhaust ventilation in areas where the notified polymer (and pellets containing the notified polymer) will be weighed and handled. The use of respiratory protection would also help to minimise inhalation exposure to the notified polymer. The risk posed by the notified polymer upon inhalation is unknown. However, due to its molecular weight being <10,000 Da., it is assumed that normal lung clearance mechanisms would not be overloaded and the notified polymer would be expelled following repeated inhalation of a small amount of respirable particles.

Overall, the OHS risk presented by the notified polymer is not expected to be unacceptable assuming that measures are taken to minimise dust levels as much as possible.

The Australian recommended exposure standard for dust is 10 mg/m³ [NOHSC 3008:(1995)], but a recommended exposure limit of 3 mg/m³ has been suggested by the American Conference of Governmental Industrial Hygienists (ACGIH) for “respirable (insoluble) particulates (not otherwise regulated)”. Dust levels should be minimised as much as possible, particularly during manual transfer of the notified polymer from the imported packaging into the mixing tank. A correctly fitted particle filter mask or respirator should be worn by workers involved in manual transfer of the notified polymer to avoid inhalation of dust particles.

Public Health Risk Assessment

The notified polymer will not be available to the public. Therefore the public will not be exposed to the notified polymer as such. However, members of the public may make dermal contact with a range of articles containing the notified polymer. However, exposure is not expected because the notified polymer (making up <1% of the finished thermoplastic articles) will be bound within a matrix and is unlikely to be bioavailable. Therefore, the risk to public health is not considered to be unacceptable, given the negligible anticipated exposure and the low hazard of the notified polymer as partially indicated by toxicological studies.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation

No ecotoxicological data were submitted. Some classes of anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This does not apply to the notified polymer.

Environmental Risk Assessment

The imported notified polymer will be manufactured into thermoplastic articles in Australia. Release from accidental spills during transport, manufacture of the masterbatch (pellets) and finished articles, and cleaning of equipment and containers is expected to be minimal. The waste (estimated to be <4% total import volume) will be disposed to landfill. Once manufactured into articles, the notified polymer will be bound within the solid matrix of the thermoplastic article. The notified polymer will share the fate of the article and, at the end of its useful life, the article is expected to be disposed to landfill. In landfill, the notified polymer is likely to be immobile due to its limited water solubility and physical containment within the matrix of the articles, and it is expected to eventually degrade by biotic and abiotic processes to form water and oxides of carbon. The notified polymer is not likely to bioaccumulate due to its relatively high molecular weight, and limited potential for exposure to the aquatic environment.

8. CONCLUSIONS AND RECOMMENDATIONS**Human health risk assessment**

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment

Based on 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 safe work and engineering practices to minimise occupational exposure to the notified polymer as introduced in powder form:
 - Ensure adequate ventilation is in place to minimise dust levels.
 - Avoid contact with eyes
 - The level of atmospheric dust should be maintained as low as possible. The Australian recommended exposure standard for dust is 10 mg/m³ [NOHSC 3008:(1995)]. The ACGIH exposure standard for atmospheric dust is 3 mg/m³.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during the application where dust may be generated:
 - Correctly fitted particle filter mask or respirator (adequate for respirable particle sizes)

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 and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from [dispersant for use in thermoplastics](#), or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - [the notified polymer 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 provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

BIBLIOGRAPHY

- NOTOX B.V. (2009a) Notified polymer: Assessment of Acute Oral Toxicity in the Rat (Acute Toxic Class Method). NOTOX Project 489576. 's-Hertogenbosch, The Netherlands. 3 April 2009. (Unpublished report provided by notifier)
- NOTOX B.V. (2009b) Notified polymer: Acute Skin Irritation/Corrosion Study in the Rabbit (4-Hour Semi-Occlusive Application). NOTOX Project 489577. 's-Hertogenbosch, The Netherlands. 3 April 2009. (Unpublished report provided by notifier)
- NOTOX B.V. (2009c) Notified polymer: Acute Eye Irritation/Corrosion Study in the Rabbit. NOTOX Project 489578. 's-Hertogenbosch, The Netherlands. 3 April 2009. (Unpublished report provided by notifier)