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

FULL PUBLIC REPORT

Solsperse 71000

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
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FULL PUBLIC REPORT

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|------------------------|
| Solsperse 71000 |
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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Orica Australia Pty Ltd (ABN 990 041 178 28)
1 Nicholson Street
MELBOURNE VIC 3000

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name, Other names, Molecular formula, Structural formula, Molecular weight, Spectral data, Methods of detection and determination, Impurities, Additives/Adjuvants, Import volume, Confidential details of use, Residual Monomers, Polymer Constituents, Identity of manufacturer, Analogue data.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Boiling point, Vapour pressure, Hydrolysis as a function of pH, Partition coefficient, Adsorption/Desorption, Dissociation constant, Flammability limits, Autoignition temperature, Explosive properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

NOTIFICATION IN OTHER COUNTRIES

UK

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Solsperse 71000

OTHER NAME(S)

Polyether amido acid polyamine derivative

MOLECULAR WEIGHT

$M_n > 10,000$ Da

ANALYTICAL DATA

Reference NMR, IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: A clear yellow to brown liquid

| Property | Value | Data Source/Justification |
|---|--------------------------------------|---|
| Boiling Point | Not determined | Expected to decompose before boiling at > 100 °C. |
| Density | 1000 kg/m ³ at 23°C | MSDS |
| Vapour Pressure | < 10 ⁻⁸ kPa | Estimated based on the molecular weight. |
| Water Solubility | 8 × 10 ⁻⁵ g/L at 22°C | Estimated based on the measured water solubility of an analogue polymer. |
| Hydrolysis as a Function of pH | Not determined | Given the low water solubility, it is expected to be hydrolytically stable in the environmental pH range (4–9) despite containing hydrolysable functionalities. |
| Partition Coefficient (n-octanol/water) | Not determined | Expected to partition into n-octanol from water based on the apparent solubility of the polymer in organic solvents and its low solubility in water. |
| Adsorption/Desorption | Not determined | Expected to partition strongly from water to soil and sediment based on its chemical structure and cationic form. |
| Dissociation Constant | Not determined | Based on the pKas for simpler compounds (3–5 and 10–11), the components of the notified polymer will remain ionised over the full environmental pH range. |
| Particle Size | Not determined. | Liquid at 20°C. |
| Flash Point | > 300°C | MSDS |
| Flammability | Not expected to be highly flammable. | Based on measured flash point. |
| Autoignition Temperature | Not determined | Not expected to autoignite under normal conditions of use. |
| Explosive Properties | Not expected to be explosive | The structural formula contains no explosives. |

DISCUSSION OF PROPERTIES

The notified polymer has a low predicted vapour pressure and water solubility, and is lipophilic.

Reactivity

The notified polymer is expected to be stable under normal storage and handling conditions.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as the neat form (> 95%) by sea.

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 |

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING

The notified polymer (> 95%) will be transported by road and rail from the port to the warehouse before distribution to customer reformulating sites in 20 or 180 kg steel drums. The reformulated products will be stored and transported in HDPE 20 L pails and 200 L drums (inks), 1, 4, 10 and 20 L steel cans and pails (coatings), and 20 and 200 L steel pails (polyols).

USE

Polymeric dispersant (used at < 10%) for use in UV cured inks and coatings (70% of import volume) and in polyols for the manufacture of polyurethane foams (30% of import volume).

OPERATION DESCRIPTION

Ink and coating formulation

At the ink and coating manufacturing sites, the notified polymer (at > 95%) will be manually weighed or metered directly from the storage drums into a stainless steel blending tank and mixed with pigments and resin to form the mill base. The mill base will then be pumped into a large mixing vessel to which the remaining additives and resin will be added to form the finished product. Samples (< 10% notified polymer) will be removed at this stage for quality control testing by laboratory technicians. The finished product (< 10% notified polymer) will be fed into containers by gravity from the bottom of the mixing vessel through a filter and filling lines.

Ink and coating application

The inks or coatings will be applied to metal, paper and plastic substrates by industry standard printing and coating techniques and cured by exposure to UV light. The ink or coating formulations (< 10% notified polymer) will be manually poured or pumped from the containers into the reservoirs of the equipment used to apply the inks and coatings. Any residual ink or coating solution remaining in the container will be scraped from the container and added to the ink or coating reservoir. Following the charging of the equipment the process will be fully automated. The used inks and coating containers will either be washed on site or sent to licensed drum recyclers.

Formulation of polyol and polyurethane foam

The notified polymer (> 95%) will be added to the blending vessel from the inverted storage drums via a pipe that is added to the drum via a bunghole. After the addition of further additives to form the polyol resin premix and conditioning, a small amount (< 10% notified polymer) will be sampled by laboratory technicians via a sampling valve in the blending vessel for quality control testing.

During the polyurethane foaming production process, the resin premix (< 10% notified polymer) will be pumped out of the blend tank to a high-pressure mechanical impingement mix head, where the resin premix will be mixed with other components of the polyol. The resulting foam mixture (< 1% notified polymer) will be dispensed from the mix head into an open mould (batch process) or onto a conveyor belt (continuous process). On occasions, depending on the manufacturer, a closed mould injection system will be employed.

In the batch process, the premix resin will be added to heated moulds and allowed to cure for about 5 minutes.

In the continuous process, once the foaming material is applied to the conveyor belt, the mixture will foam and cure into the final solid product within 3-5 minutes. From the final product, foam blocks will be cut in varying lengths from 3-60 metres for further processing.

After production the articles are often further processed; paint, fabric wrapping and other components may be added.

The used drums will be cleaned by filling with an appropriate cleaning solvent and the contents pumped to pits for storage prior to disposal by a licensed waste management company.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

| <i>Category of Worker</i> | <i>Number</i> | <i>Exposure Duration (hours/day)</i> | <i>Exposure Frequency (days/year)</i> |
|---------------------------|---------------|--|---|
| Transport | 6-8 | 2-3 | 10-15 |
| Coating/Ink | | | |
| Blending | 4 | 8 | 50 |
| Laboratory | 2 | 1 | 20 |
| Application | 6-8 | 4 | 260 |
| Polyol | | | |
| Blending | 1 | 2 | 260 |
| Laboratory | 1 | 1 | 260 |
| Foam manufacturing | 2-4 | 1 | 260 |

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are not expected to be exposed to the notified polymer (> 95%) except in the unlikely event of an accident.

Ink and coating formulation

Dermal and ocular exposure to the notified polymer (> 95%) may occur when manually weighing and charging the blending vessels and when taking samples (< 10% notified polymer) from the blending vessel by laboratory technicians. Inhalation exposure to vapours and aerosols is not likely during blending due to the low vapour pressure of the notified polymer.

Application of inks and coatings

Dermal and ocular exposure may occur to the notified polymer (< 10%) when manually adding the formulated ink or coating products to the reservoirs, when scraping residuals from the used containers for re-use and subsequent cleaning prior to recycling, and when maintaining and cleaning the application equipment. Although workers will make dermal contact with the notified polymer when handling cured end products, the notified polymer will be reacted into the polymer matrix and hence not bioavailable.

Formulation of polyol and polyurethane foam

Dermal and ocular exposure to the notified polymer (> 95%) may occur when connecting and disconnecting transfer lines from the drums to the blending vessels and when taking samples (< 10% notified polymer) from the blending vessel by laboratory technicians. Following the charging of the equipment the process is fully automated and thus exposure is not expected.

During polyurethane foam manufacture and equipment maintenance significant exposure to the notified polymer is not expected as the notified polymer will be reacted into the polyurethane matrix in the foam and will not be bioavailable. However, dermal and ocular exposure may occur to the notified polymer (< 10%) when cleaning the used drums prior to recycling.

In all cases where exposure to the notified polymer may occur, it is stated by the notifier that personal protective equipment, such as coveralls, safety goggles and gloves, will be used by workers to limit exposure.

6.1.2. Public exposure

The public will be exposed to the notified polymer as a result of dermal contact with coated surfaces and damaged articles with exposed polyurethane foam. However, the notified polymer will not be bioavailable as it will be reacted into the polymer matrix once dried or cured.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

| <i>Endpoint</i> | <i>Result and Assessment Conclusion</i> |
|---|---|
| Rat, acute oral toxicity | LD50 > 2000 mg/kg bw; low toxicity |
| Rabbit, acute dermal toxicity* | LD50 > 2000 mg/kg bw; low toxicity |
| Mutagenicity – bacterial reverse mutation | non mutagenic |

* MSDS – study report not submitted

Toxicokinetics, metabolism and distribution.

Given the high molecular weight (> 10,000 Da) and low water solubility of the notified polymer, absorption across biological membranes is unlikely. This prediction is supported by the lack of effects observed in the available toxicological studies.

Acute toxicity.

The notified polymer has a low acute oral toxicity. Furthermore, based on data given in the MSDS, the notified polymer has a low acute dermal toxicity.

Irritation and Sensitisation.

The notified polymer is not likely to present as a sensitiser, as it is not expected to significantly penetrate the stratum corneum, and so is unlikely to cause allergic contact dermatitis.

Based on structural alerts the notified polymer may present as an irritant, although given the high molecular weight and insignificant amounts of oligomeric species present, the potential for irritancy is expected to be at most slight (Hulzebos, 2005).

Mutagenicity.

The notified polymer was shown to not cause mutagenic effects in an Ames test. No other genotoxicity data were available.

Health hazard classification

The notified polymer may present as a slight eye and skin irritant. Based on the available data it 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

Due to the limited available information, the hazard of the notified polymer is uncertain. However, based on structural alerts, irritancy of unknown severity is possible.

Workers potentially at risk of irritation will be those handling the notified polymer in the neat form.

Given the low potential hazard, the proposed use of PPE and the engineering controls in place, the risk to workers using the notified polymer is not considered to be unacceptable.

6.3.2. Public health

Given the public will not be exposed to the notified polymer in a bioavailable form, the risk to 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 release of the notified polymer to the environment during importation, storage, and transport is unlikely. The most likely reason for a release to the environment during these activities will be a transport accident. However, the capacity and specifications of the import containers are likely to reduce the extent of any such releases. Those releases that do occur as a result of accidents are expected to be physically contained, absorbed on inert material, and either reused or sent for safe disposal.

Polyol formulation

The release of the notified polymer at the polyol reformulation site is likely to be limited by the engineering controls that are employed. For example, only 0.2% of formulated liquid polyol product is expected to remain as residues in the lines at the end of blending. This quantity of residual product is equivalent to 18 kg of notified polymer ($= 0.2\% \times 30\%$ of annual import volume), which will be either recycled or removed by a waste disposal company for incineration or, more likely, disposed of to landfill. Any spills that are likely to occur during formulation will be contained in the existing bunded areas of the production facility and will be removed by a waste disposal company for disposal by incineration, or to landfill. Leaking drums and any clean-up material such as rags are likely to be stored on-site in oversized containers or drums until they are removed by a waste disposal company for disposal in landfill.

It is estimated that up to 2% of the formulated product, equivalent to 180 kg of notified polymer ($= 2\% \times 30\%$ of annual import volume), will be discharged to the sewer with the wash waters (after on-site treatment to remove organic solvents and insoluble substances including the notified polymer) as a result of spill clean up and equipment cleaning.

Residues in import drums may be either removed by the waste disposal company for incineration or disposal in landfill, or the drums may be recycled with the contents mostly likely being discharged to a sewage treatment plant after on-site treatment to remove organic solvents and insoluble substances ($90 \text{ kg} (= 1\% \times 30\%$ of annual import volume)).

Ink and Coating Manufacture

The notifier has estimated that approximately 105 kg of the annual introduction volume of notified polymer ($= 0.5\% \times 70\%$ of annual import volume) will be lost as result of spillages that occur during ink and coating manufacture. The spillages will be absorbed and the materials collected will be disposed of to landfill or incinerated. A maximum of 210 kg of notified polymer ($= 1\% \times 70\%$ of annual import volume) will remain in import drums that will be collected by licensed waste contractors. It is expected that residue from the drums will be released to sewage treatment plants after treatment to remove organic solvents and insoluble substances by the licensed waste contractors.

RELEASE OF CHEMICAL FROM USE

Polyurethane manufacture

The manufacture of polyurethane articles from the polyol product containing the notified polymer takes place on an industrial scale using various blending, pumping and injection processes. Although not specified, the release of the notified polymer from the manufacture of polyurethane is expected to be limited to accidental spills of liquid polyol formulations, the disposal of liquid residues from blending vessels and liquid transfer lines, and the disposal of residual polyol formulation present in drums. Based on a typical wastage figure of 2% for clean up of processing equipment and 1% residues in drums, up to 270 kg of notified polymer ($= 3\% \times 30\%$ of annual import volume) may require disposal from the manufacture of polyurethane articles. It is expected that these liquid wastes will be stored on-site for subsequent disposal. This may involve incineration of the organic components or, again more likely, disposal to landfill sites.

Application of inks and coatings

The potential for release of the notified polymer to occur as a result of the application of UV-curable inks and coating products to articles (mainly wood) will depend on the specific application techniques employed. Since UV curing is carried out after coating, this is likely to be done only at industrial sites. For application of coatings by rollers or dipping, the wastage figure is expected to be about 2% of the applied volume of liquid.

These wastes would be expected to be captured, solidified, and subsequently disposed of to landfill as solid wastes. Similarly, the wastage resulting from the application of inks to surfaces by the use of rollers may be up to 2% of the applied volume with the wastes captured and solidified for disposal to landfill. Some additional wastes (2% of the applied volume) may be generated as a result of the clean up of containers and application equipment, but these liquid wastes are expected to be stored on-site for subsequent disposal. As for the wastes generated in the manufacture of polyurethane, this may involve incineration of the organic components including the notified polymer or disposal to landfill sites.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer is irreversibly combined with other chemical substances as part of the manufacture of articles. In the case of polyurethane manufacture, polyol products containing the notified polymer are completely reacted by cross-linking, which leaves no residual material in the finished article. The finished polyurethane articles will be disposed of to landfill at the end of their useful life. In the case of printing and coating applications, the notified polymer is immobilised within a UV-cured polymeric film on coated articles. The notified polymer will be disposed of along with the used article at the end of its useful life, which, in the majority of cases, will be to landfill. In cases where UV-curable inks containing the notified polymer are used on paper, there is some potential for release of the notified polymer during the de-inking stage of paper recycling. However, very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer.

7.1.2 Environmental fate

The majority of the imported quantity of notified polymer will be either irreversibly combined with articles or disposed of to landfill with solid wastes generated by the coating of articles. Hence, there are limited opportunities for release of the notified polymer to the environment except as a result of accidents. The major proportion of the mass of the small quantities of notified polymer that may enter the sewage treatment system as a result of the manufacturing process is expected to strongly adsorb to soil, sediment and organic matter in sewage treatment plants. This quantity of notified polymer will therefore be removed with sewage sludge and will not be released to aquatic ecosystems with the treated wastewater. Similarly, any quantities of the notified polymer that may be released as a result of de-inking processes in paper recycling will associate with the sludge that is generated. This sludge will be dried and incinerated or sent to landfill for disposal. The notified polymer is not expected to be mobile within soils and sediments as a result of its low water solubility and anticipated strong adsorption to solids. The notified polymer is not expected to be biodegradable, but it will not bioaccumulate.

7.1.3 Predicted Environmental Concentration (PEC)

Based on the available information, a small quantity of the notified polymer (expected to be < 2% of the annual import volume) could enter the sewage system annually as a result of the reformulation of the imported quantity of polymer into new liquid products or recycling of paper. However, this figure is likely to be an overestimate as these potential releases are expected to arise mainly from the disposal of liquid cleaning wastes from the reformulation sites, which, in modern facilities, is expected to be via an on-site solvent and insoluble solids removal system. Based on the low water solubility of the notified polymer and its expected tendency to adsorb to solids, this type of system would remove the majority of the entrained polymer prior to release of the aqueous wastes into the sewer system. As discussed in Section 7.1.2, any quantities of the notified polymer in wastewater entering a sewage treatment plant are expected to be removed with the bio-solids produced in such plants. The overall fraction of notified polymer that could enter aquatic ecosystems through the sewage treatment systems as a result of wastages from the reformulation process or paper recycling is therefore likely to be significantly below the nominal 2% release figure indicated above. As no significant environmental releases of the notified polymer are expected to occur based on the intended use pattern, no PEC has been calculated.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on two species of freshwater green algae with the notified polymer and an acceptable analogue are summarised in the table below. Details of these studies can be found in Appendix C.

| <i>Algal Toxicity</i> | <i>Result</i> | <i>Assessment Conclusion</i> |
|----------------------------------|------------------------|---|
| <i>Selenastrum capricornutum</i> | EC50 0.53 mg/L | The notified polymer is highly toxic to algae |
| <i>Scenedesmus subspicatus</i> | EL50 > 1000 mg/L (WAF) | An acceptable analogue for the notified polymer is not harmful to algae up to the limit of its water solubility |

A limit test of the toxicological effects of an analogue polymer on *S. subspicatus* according to the appropriate OECD Test Guideline indicated no harmful effects on this species up to the limit of the water solubility of an analogue of this substance (0.08 mg/L). This result is not consistent with the effects testing of the notified polymer on *S. capricornutum*. Although this latter test was carried out possibly using a non-standard test method, a clear dose-response in the toxicity profile was observed and, at the highest nominal test concentration, lethal effects of the notified polymer on algae were found. The reasons for the apparently markedly different sensitivity of green algae to these two closely related polymers are unclear from the results provided. However, the effects of the notified polymer on algae, particularly the evidence of algicidal activity, indicate that this polymer is likely to have significant adverse effects on at least one trophic level of aquatic ecosystems, if it is released into waterways in significant quantities.

The notified polymer is not expected to cross biological membranes or bioaccumulate based on the relatively high molecular weight of the notified polymer constituents and their ionic form in the environmental pH range.

7.2.1 Predicted No-Effect Concentration (PNEC)

The notified polymer is not likely to be released into aquatic ecosystems in ecotoxicologically significant concentrations. It is therefore not necessary or meaningful to calculate the environmental risk quotient for potential releases of the notified polymer. However, the PNEC for the notified polymer has been calculated. In this calculation, an assessment factor of 1000 was used, as acute toxicity end-points are available for only one trophic level of aquatic ecosystems. Hence, the PNEC for the notified polymer based on the toxicity to freshwater algae is 0.53 µg/L (= 0.53/1000 mg/L).

7.3. Environmental risk assessment

The notified polymer is unlikely to be released into aquatic ecosystems in environmentally significant concentrations based on the intended use pattern and the potential for removal of the polymer from wastewater streams by physical processes, especially adsorption to solids. Thus, although the notified polymer is potentially hazardous to algae, there is currently a low risk to aquatic organisms based on the lack of pathways for aquatic exposure to the polymer. Therefore, the risk of an adverse effect on the environment from the intended use of the notified polymer is acceptably low.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

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

and

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 presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

| | <i>Hazard category</i> | <i>Hazard statement</i> |
|---------------|------------------------|--|
| Environmental | Acute Category 1 | Very toxic to aquatic life |
| | Chronic Category 1 | Very toxic to aquatic life with long lasting effects |

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

On the basis of 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 ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Coveralls
 - Impermeable gloves
 - 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 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 polymer should be disposed of to landfill.

Storage

- Keep the container tightly closed in a dry and well-ventilated area.

Emergency procedures

- Spills or accidental release of the notified polymer should be prevented from entering drains and waterways. Use absorbent material to collect and seal in properly labelled containers or drums for 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;
 - uses are proposed which significantly increase exposure to the aquatic compartment.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a polymeric dispersant used in inks, coatings and in polyols for the manufacture of polyurethane foams, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 30 tonnes per annum, or is likely to increase, significantly;
 - if 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.

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.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility

8×10^{-5} g/L at 22°C (Acceptable analogue of notified polymer)

Remarks

The solubility of the notified polymer in water was estimated as 1.1 g/L in a visual test based on a shake-flask technique (Leeder, 2007). This result nominally indicates that the notified polymer is readily soluble in water. However, this result is not consistent with a quantitative water solubility test performed on an acceptable analogue of the notified polymer which showed that the solubility in water of the analogue at $22 \pm 1^\circ\text{C}$ is 0.08 mg/L (Intertek ASG, 2005); this analogue polymer is an analogue for both the notified polymer and for another analogue polymer used in an ecotoxicological study. This test was carried out in duplicate using a turbidimetric analytical technique to monitor the solubilisation of the analogue polymer as an initially turbid mixture of the polymer in water was diluted. This latter quantitative test is considered to be a more reliable indicator of the solubility of the notified polymer in water. Based on this result, the notified polymer and the analogue polymer used to evaluate toxicity to *Scenedesmus subspicatus* are both only very slightly soluble in water.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

| | |
|------------------|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. |
| Species/Strain | Rat/Spague-Dawley CD strain |
| Vehicle | Arachis oil BP |
| Remarks - Method | No significant protocol deviations |

RESULTS

| <i>Group</i> | <i>Number and Sex of Animals</i> | <i>Dose mg/kg bw</i> | <i>Mortality</i> |
|--------------|--------------------------------------|--------------------------|------------------|
| 1 | 3 F | 2000 | 1/3 |
| 2 | 3 F | 2000 | 0/3 |

| | |
|-------------------|--|
| LD50 | > 2000 mg/kg bw |
| Signs of Toxicity | No signs of systemic toxicity. No treatment related changes in bodyweight were noted. |
| Effects in Organs | No abnormalities detected at necropsy. |
| Remarks - Results | One animal was found dead 6 days after dosing in Group 1. Necropsy was not performed on this animal. |

| | |
|------------|---|
| CONCLUSION | The notified polymer is of low toxicity via the oral route. |
|------------|---|

| | |
|---------------|-------------------|
| TEST FACILITY | Safepharm (2005a) |
|---------------|-------------------|

B.2. Genotoxicity – bacteria

| | |
|----------------------------------|---|
| TEST SUBSTANCE | Notified polymer |
| METHOD | OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure |
| Species/Strain | <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100. <i>E. coli</i> : WP2 uvrA ⁻ . |
| Metabolic Activation System | S9 fraction from phenobarbital and β -naphthoflavone induced male rat livers. |
| Concentration Range in Main Test | a) With metabolic activation: 5 – 5,000 μ g/plate. b) Without metabolic activation: 5 – 5,000 μ g/plate. |
| Vehicle | Acetone |
| Remarks - Method | No significant protocol deviations. |

RESULTS

| Metabolic Activation | Test Substance Concentration (µg/plate) Resulting in: | | | |
|--------------------------|---|---|---------------|------------------|
| | Cytotoxicity in Preliminary Test | Cytotoxicity in Main Test | Precipitation | Genotoxic Effect |
| <i>Absent</i> | | | | |
| Test 1 (range finder) | 500 (<i>Salmonella</i> strains) > 5000 (<i>E. coli</i> strain) | ≥ 1,500 (<i>Salmonella</i> strains) > 5000 (<i>E. coli</i> strain) | ≥1,500 | None |
| Test 2 (main test) | | ≥ 1,500 (<i>Salmonella</i> strains) > 5000 (<i>E. coli</i> strain) | ≥1,500 | None |
| <i>Present</i> | | | | |
| Test 1 (range finder) | > 5,000 | ≥ 1,500 (<i>Salmonella</i> strains) > 5000 (<i>E. coli</i> strain) | ≥1,500 | None |
| Test 2 (main test) | | ≥ 1,500 (<i>Salmonella</i> strains) > 5000 (<i>E. coli</i> strain) | ≥1,500 | None |

Remarks - Results

The notified polymer caused a visible reduction in the growth of the bacterial background lawn to all of the *S.typhimurium* tester strains at 1,500 µg/plate. No toxicity was observed to the *E.coli* tester strain, WP2uvrA⁺. The test material was, therefore, either tested up to the maximum recommended dose level of 5,000 µg/plate or its toxic limit, depending on strain type.

A greasy precipitate was observed at and above 1,500 µg/plate, this did not prevent the scoring of revertant colonies.

No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, at any dose level either with or without metabolic activation.

All of the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

Safepharm (2005b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C 1.1. Algal growth inhibition test

| | |
|----------------------------|--|
| TEST SUBSTANCE | Notified polymer |
| METHOD | Brixham Environmental Laboratory SOP BA285 |
| Species | <i>Selenastrum capricornutum</i> |
| Exposure Period | 72 hours (static) |
| Concentration Range | 0.010 – 3.2 mg/L |
| Nominal | 0.010, 0.032, 0.10, 0.32, 1.0 and 3.2 mg/L |
| Concentration Range Actual | Not reported |
| Auxiliary Solvent | Acetone |
| Water Hardness | Not reported |
| Analytical Monitoring | None |
| Remarks – Method | <p>The test consisted of a solvent control and six nominal test concentrations of the notified polymer. A 32000 mg/L colourless stock solution of the test substance was prepared by dissolving 160 mg of the notified polymer in 5.0 mL of acetone. The 3.2 mg/L aqueous test solution was prepared from this stock and the remaining test solutions were prepared by serial dilution of the nominal 3.2 mg/L solution with unspecified dilution water. The maximum level of solvent in the test solutions did not exceed 100 µL/L.</p> <p>The test was run at 24±2°C under static conditions. The initial cell density was reported as 0.25×10^4 cell mL⁻¹, but the measurement technique was not specified. No other experimental parameters were provided. No positive toxicity control substance was employed.</p> |

RESULTS

| Nominal concentration (mg L ⁻¹) | Algal cell density after 72 h ($\times 10^4$ cell mL ⁻¹) | % Inhibition (Growth rate) |
|---|--|-------------------------------|
| Solvent control | 124 | - |
| 0.010 | 125 | 0 |
| 0.032 | 132 | 0 |
| 0.10 | 18.2 | 31 |
| 0.32 | 17.7 | 31 |
| 1.0 | 0.40 | 92 |
| 3.2 | <0.001 | 100 |

Remarks – Results

The algal cell density in the solvent control increased by 496-fold over the 72 hour period of the test which indicates that the residual solvent in the test solution does not significantly inhibit cell growth under the conditions of this test. The significant increase in cell density in this control sample also indicates that the test conditions were sufficient to allow rapid algal growth and that the conditions were therefore sufficient to allow potential adverse effects of the notified polymer on algal growth to be revealed.

The nominal concentrations of the notified polymer in this test span a range above and below the likely water solubility of this polymer (0.08 mg/L). However, no indication was provided in the report of any significant phase separation in the test solutions.

Based on the reported algal growth data, the notified polymer does not inhibit the growth of freshwater green algae at nominal concentrations ≤ 0.032 mg/L. However, the polymer has a pronounced and dose-responsive inhibitory effect on algal growth rates at nominal test concentrations ≥ 0.1 mg/L. At the highest nominal test concentration (3.2 mg/L), the notified polymer displays algicidal effects as indicated by a very substantial reduction of algal cell density below initial levels.

By inspection of the dose-response curve, the EC₅₀ (growth rate) for the notified polymer based on nominal concentrations is in the range 0.32–1.0 mg/L. This end-point is more precisely estimated as 0.53 mg/L by linear interpolation of the percentage inhibition of cell growth at each nominal test concentration using ToxCalc (2005). Based on this analysis, the toxicity of the notified polymer is significantly less than the 1 mg/L threshold classified as very toxic to aquatic life. Hence, the notified polymer is classified as very toxic to algae.

| | |
|---------------|---|
| CONCLUSION | The notified polymer is very toxic to algae |
| TEST FACILITY | Brixham Environmental Laboratory (2005). |

C 1.2. Algal growth inhibition test

| | |
|-----------------------|---|
| TEST SUBSTANCE | Analogue polymer |
| METHOD | OECD TG 201 Alga, Growth Inhibition Test – Limit test. EC Directive 92/69/EEC C.3 Algal Inhibition Test. |
| Species | <i>Scenedesmus subspicatus</i> |
| Exposure Period | 72 hours |
| Nominal Concentration | 1000 mg/L (WAF) |
| Auxiliary Solvent | None |
| Water Hardness | Not reported |
| Analytical Monitoring | None |
| Remarks – Method | A preliminary 72-hour range finding test was performed at three nominal loading rates of 10, 100 and 1000 mg/L. The test solutions were prepared as water accommodated fractions (WAFs) in a standard culture medium using a mid-depth siphoning technique. The preparation of WAFs was necessary as microscopic examination of the initially prepared samples confirmed the presence of significant quantities of dispersed solids in the water phase. |

For the limit test, *Scenedesmus subspicatus* was exposed to the analogue polymer at a single nominal loading rate of 1000 mg/L (six replicate flasks) for 72 hours under constant illumination and with shaking at a temperature of 24±1°C. The test sample was prepared as a WAF by mid-depth siphoning from a suspension of the analogue polymer in standard culture medium. The WAF was clear and colourless and was inspected microscopically to confirm the absence of micro-dispersions or undissolved test material. Samples of the algal populations were removed daily and the cell concentrations were determined for each control and treatment group using a Coulter® Multisizer Particle Counter. The algae in test and control cultures were examined microscopically after the 72-hour exposure period. No positive toxicity control test was performed.

RESULTS

| Biomass | | Growth | |
|---------------------------|--------------|---------------------------|--------------|
| E_bL*50 mg/L at 72 h | NOEL mg/L | E_rL*50 mg/L at 72 h | NOEL mg/L |

| >1000 (WAF) | 1000 (WAF) | >1000 (WAF) | 1000 (WAF) |
|--------------------------|---|-------------|------------|
| *EL = Effective loading. | | | |
| Remarks – Results | <p>Based on observations of cell density, temperature and pH, the test is considered valid.</p> <p>In the range finding test, growth stimulation with respect to the control (6–26%) was observed for all three nominal concentrations of the analogue polymer. Similarly, in the limit test, 6% growth stimulation was observed for a nominal test concentration of 1000 mg/L after 72 hours of exposure. Microscopic observations of test and control cultures from the limit test at the end of the exposure period did not reveal any abnormalities in the algae.</p> <p>Based on these results, the 72-hour no-observed effect loading rate (NOEL) for the analogue polymer is 1000 mg/L (WAF). By inspection, the 50% inhibition of cell growth end-point based on the nominal loading level of the WAF is >1000 mg/L for both the biomass and growth-rate measures of inhibition. However, as the water solubility of an analogue to this polymer has been determined as 0.08 mg/L, these end-points do not accurately characterise the toxicity of this analogue polymer to freshwater green algae. In this case, it is more appropriate to classify the toxicity of this analogue polymer to algae as not harmful up to its water solubility limit.</p> | | |
| CONCLUSION | This analogue polymer is not harmful to algae up to the limit of its water solubility. | | |
| TEST FACILITY | Safepharm (2006) | | |

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