File No PLC/1327

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

**POLYMER OF LOW CONCERN PUBLIC REPORT**

**Polymer in EasySperse™**

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of the Environment.

This Public Report is 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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# SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

| ASSESSMENT REFERENCE | APPLICANT(S) | CHEMICAL OR TRADE NAME | HAZARDOUS SUBSTANCE | INTRODUCTION VOLUME | USE |
|---|---|---|---|---|---|
| PLC/1327 | ISP (Australasia) Pty Ltd | Polymer in EasySperse™ | No | ≤ 15 tonnes per annum | Dispersant in agricultural products |

# CONCLUSIONS AND REGULATORY OBLIGATIONS

**Human Health Risk Assessment**
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

**Environmental Risk Assessment**
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

**Health and Safety Recommendations**

- 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.

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m$^3$.

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in liquid formulations:
  - If liquid aerosols are formed during the use of the notified polymer, engineering controls and respiratory protection should be used to minimse inhalation exposure.

- 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 *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

**Disposal**

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

**Emergency Procedures**

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

**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 being a dispersant of agricultural products, 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 notified 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 products containing the notified polymer was provided by the applicant. The accuracy of the information on the MSDS remains the responsibility of the applicant.

# ASSESSMENT DETAILS

## 1. APPLICANT AND NOTIFICATION DETAILS

**Applicants**
ISP (Australasia) Pty Ltd (ABN: 27 000 011 923)
Suit 603, Level 6
2 Burbank Place
Norwest Business Park
BAULKHAM HILLS NSW 2153

**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, spectral data, purity, polymer constituents, residual monomers/impurities, use details and manufacture/import volume and site of manufacture/reformulation.

## 2. IDENTITY OF POLYMER

**Marketing Name(s)**
EasySperse™ P-20 (spray-dried powder)
EasySperse™ (25% aqueous solution)

## 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 | Off-white (as powder); yellow hazy solution (25% solution) |
| Melting Point/Glass Transition Temp | Not determined |
| Density | 1,000 kg/m$^3$ at 20 °C (25% solution) |
| Water Solubility | > 250 g/L |
| Dissociation Constant | Expected to be ionised under environmental conditions (pH 4–9) |
| Particle Size | Not determined |
| Reactivity | Stable under normal use conditions |
| Degradation Products | None known |

## 5. INTRODUCTION AND USE INFORMATION

**Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years**

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| Tonnes | 5–15 | 5–15 | 5–15 | 5–15 | 5–15 |

**Use**
The notified polymer will not be manufactured in Australia. The notified polymer will be imported as neat powder in 25 kg plastic bags. It will be reformulated in Australia into liquid products containing a maximum 1% concentration of the polymer. The formulated products will be supplied as a concentrate in 1 and 5 L plastic bottles, 20 and 200 L plastic drums, or in 1,000 L intermediate bulk containers.

The notified polymer will be used as a dispersant in agricultural product formulations (foliar fertiliser) for on farm use. A recommended 100 fold dilution of the formulated product (0.01% final polymer concentration) in water will be applied mostly by ground boom spray at a rate of 5 L product per hectare to vegetable crops.

## 6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

| *Endpoint* | *Result* | *Effects Observed?* | *Test Guideline* |
|---|---|---|---|
| Rat, acute oral | LD50 > 2,000 mg/kg bw | no | OECD TG 425 |
| Rat, acute dermal | LD50 > 2,098 mg/kg bw | yes | OECD TG 402 |
| Rabbit, eye irritation | non-irritating | yes | OECD TG 405 |
| Rabbit, skin irritation | non-irritating | yes | OECD TG 404 |
| Genotoxicity – bacterial reverse mutation | non mutagenic | No | OECD TG 471 |

All results were indicative of low hazard.

*Acute dermal toxicity*
At 24 hour, 6/10 rats demonstrated slight dermal effects, which ranged from absent to severe at day 7. All animals showed complete recovery at the end of the observation period. In three animals, wetness of the anogenital area were noted from day 0 to 2 and one of these animals showed alopecia from day 2 to 12. Body weight change in 9/10 animals were found to be normal. No abnormalities were noted at necroscopy. The dermal $LD_{50}$ of the notified polymer was reported to be greater than 2,098 mg/kg bw.

*Eye irritation*
All animals showed conjunctival irritation, which was cleared by 72 hours. No corneal opacity or iridial damage was observed during the test period.

*Skin irritation*
Application of the test substance to the skin of rabbits produced very slight to moderate erythema within the first 24 hours but receded by day 7. The study authors concluded that some of the initial observations of skin irritation were due to the technique for removing test article rather than the substance itself.

**Occupational Health and Safety Risk Assessment**
The notified polymer meets the PLC criteria and is therefore assumed to be of low health hazard. This is supported by toxicology tests submitted on the notified polymer.

Dermal and ocular exposure to the notified polymer could occur during various processes such as reformulation and when preparing the diluted fertiliser for application. Reformulation will take place under local and general ventilation and workers will also wear suitable dust musk, safety goggles, gloves, overalls and safety boots.

In addition, given that the fertiliser will be applied by spray application, there is also potential for inhalation exposure of the notified polymer (typically 0.01% concentration) to the farm workers. The notifier states that the fertiliser will be applied using ground spray boom behind a tractor, which will produce a relatively coarse spray with little mist being generated. To avoid spray drift, the spray application will not take place on windy days.

Inhalation of water insoluble polymers with high molecular weights has been linked with irreversible lung damage due to lung overloading and impaired clearance of particles from the lung, particularly following repeated exposure. Although the notified polymer is of high molecular weight > 10,000 Da, it has significant water solubility and, therefore, if inhaled at low levels during spray application it is likely to be cleared from the upper respiratory tract readily through mucociliary action. Small proportions of the notified polymer may reach the lower respiratory tract, but it should still be cleared from the lungs. If high concentrations of the notified polymer are inhaled, clearance from the lungs may occur more slowly. The risk to workers during spray application would be minimised by through the use of an enclosed vehicle during spray application or respiratory protection.

Overall, based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

**Public Health and Safety Risk Assessment**
The notified polymer will not be made available to the general public. Given the assumed low hazard, the risk posed by exposure to the notified polymer is not considered unreasonable.

## 7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Anionic polymers are generally of low toxicity to fish and daphnia, however they 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, which may apply to the notified polymer. However, the toxicity to algae is likely to be reduced due to the presence of calcium ions in environmental waters, which will bind to the functional groups.

The notified polymer will be imported neat into Australia as a dispersant for reformulation into agricultural product formulations. Blending equipment is expected to be washed with water, and the rinsate re-used in subsequent blending processes. Release of the notified polymer to the environment during import, reformulation, storage, and transport is expected to be limited to accidental spills or leaks and residue in import packaging (estimated by the notifier to be a total of 2% of the import volume, or 300 kg). Spills or accidental release of the products containing the notified polymer are expected to be collected with adsorbents and disposed of to landfill in accordance with local government regulations.

Products containing the notified polymer will be applied to agricultural soils in a dilute form. Application is expected to be to topsoil by ground boom spraying, which will produce a relatively coarse spray and minimise the generation of fine mist. During use the notified polymer may also be released to the environment as accidental spills and container residues (estimated by the notifier to be 0.5% of the import volume, or 75 kg). Residues in product containers are likely to be rinsed with water, and the rinsate added to spray tanks for application. Empty product containers are expected to be disposed of to landfill in accordance with local government regulations.

The majority of the notified polymer is expected to be applied to agricultural soils, and over time is expected to become freely available in the environment. Due to its high molecular weight, the notified polymer is not expected to volatilise to the atmospheric compartment. Based on its high water solubility and anionic properties, the notified polymer is expected to be moderately mobile in the soil compartment. Therefore, the notified polymer is expected to enter surface-waters in run-off from treated soils or from overspray or spray drift during application by ground boom spraying. Based on its molecular structure and high water solubility, the notified polymer has the potential to hydrolyse

under environmental conditions (pH 4–9). The notified polymer is not expected to cross biological membranes due to its high molecular weight, and therefore unlikely to bioaccumulate. In surface waters and in soils, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

Therefore, based on its assumed low hazard and assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.