File No.: PLC/1567

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Dispersogen SP Plus

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 and Energy.

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/1567	Clariant (Australia) Pty Ltd	Polymer in Dispersogen SP Plus	No	< 300 tonnes per annum	Dispersing agent in paints

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 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.

- A copy of the SDS should be easily accessible to employees.

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (Safe Work Australia, 2015) or relevant State or Territory Code of Practice.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of 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

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- 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 dispersing agent in paints, 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.

Safety Data Sheet

The SDS of the product containing the notified polymer was provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
Clariant (Australia) Pty Ltd (ABN No.: 30 069 435 552)
Level 3, Olympus Building
3 Acacia Place
296 – 324 Ferntree Gully Road
NOTTING HILL VIC 3168

Exempt Information (Section 75 of the Act)
Data items and details exempt from publication include: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
Dispersogen SP Plus (product containing the notified polymer at 50% concentration)

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 g/mol.

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	Pale yellow solution
Melting Point/Glass Transition Temperature	< 0 °C
Density	1,118 kg/m^3 at 25 °C
Water Solubility	> 1,000 g/L at 20 °C
Dissociation Constant	Not determined; contains potential anionic functionalities which are expected to be ionised in the environmental pH range (4–9)
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 300	< 300	< 300	< 300	< 300

Use
The notified polymer acts as a stabilising agent for silicate and organosilicate paints. The notified polymer will not be manufactured in Australia. It will be imported at < 50% concentration in 25 L, 220 kg or 1,000 L containers for reformulation into paint products. Alternatively, the notified polymer will be imported in end-use paint products at ≤ 0.5% concentration in 1 – 20 L metal cans. End-use paint products may be applied to concrete and wallpapers by spray, brush or roller and will be available for industrial and do-it-yourself (DIY) users.

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 conducted on the notified polymer (as imported at < 50% concentration) submitted on the following toxicological endpoints.

Endpoint	*Result*	*Effects Observed*	*Test Guideline*
1. Acute oral toxicity – rat	LD50 > 5,000 mg/kg bw	No	OECD TG 423
2. Skin irritation – *in vitro* EpiDerm™ Reconstructed Human Epidermis Model	non-irritant	No	OECD TG 439
3. Eye irritation – *in vitro* Bovine Corneal Opacity and Permeability test; EpiOcular™ test	non-irritant	No	OECD TG 437
4a. Skin sensitisation – *in chemico* Direct Peptide Reactivity Assay;	minimal reactivity	No	OECD TG 442C
4b. Skin sensitisation – *in vitro* human Cell Line Activation Test	No evidence of dendritic cell induction	No	OECD TG 442E
5. Genotoxicity - bacterial reverse mutation	non mutagenic	No	OECD TG 471

All results were indicative of low hazard.

In vitro skin and *in vitro* eye irritation studies were conducted to evaluate the irritation potential of the notified polymer. The notified polymer was non-irritating to the skin or eyes when tested at 50% concentration in the EpiDerm™ test or BCOP test. No significant reduction in cell viability was observed in either the *in vitro* eye irritation or skin irritation tests when compared to controls.

An *in chemico* assay and an *in vitro* cell based assay were conducted to evaluate the sensitisation potential of the notified polymer. The tests are part of an Integrated Approach to Testing and Assessment (IATA) which address specific events on the Adverse Outcome Pathway (AOP) leading to development of skin sensitisation (OECD, 2015). The tests are thus considered relevant for assessment of the skin sensitisation potential of the notified polymer, together with other supporting information. The notified polymer showed negative responses in both of the tests, suggesting that the polymer does not initiate the molecular reaction or induce dendritic cellular events associated with skin sensitisation.

The notified polymer was not mutagenic in a bacterial reverse mutation assay.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

The notified polymer is proposed for industrial and DIY use.

Workers may be exposed to the notified polymer at < 50% concentration. However, under the conditions of the occupational settings described by the notifier, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

The public may be exposed to the notified polymer at ≤ 0.5% concentration when applying end-use paint products to concrete and wallpaper surfaces. Given the low concentration of the polymer in the end-use products, when used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL RISK ASSESSMENT

The notified polymer meets the PLC criteria and can therefore be assumed to be of low hazard. The notified polymer is very soluble in water and contains functionality which will become anionic under environmental conditions (pH 4–9). Anionic polymers are generally of low toxicity to fish and daphnia but 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, leading to chelation of essential nutrients. However, the notified polymer contains functionalities that dilute the chelating effect, which would result in significantly reduced toxicity to algae. (Boethling & Nabholz,1997). This is supported by environmental endpoints observed in testing conducted on the notified polymer (as imported at < 50% concentration) on the following toxicological endpoints:

Endpoint	*Result*	*Assessment Conclusion*	*Test Guideline*
Daphnia Toxicity	EC50 > 200 mg/L	Not harmful to aquatic invertebrates	OECD TG 202
Algal Toxicity	NOEC > 200 mg/L	Not harmful to algae	OECD TG 201
Inhibition of Bacterial Respiration	NOEC > 1000 mg/L	Not harmful to bacteria in sewage sludge	OECD TG 209

All results were indicative of low hazard and the notified polymer is therefore considered to be not harmful to aquatic life.

The notified polymer will be imported into Australia as a pigment dispersant for reformulation into silicate and organo-silicate paints for industrial and DIY use. Spills or accidental release of the products containing the notified polymer during import, storage and transport are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations. As estimated by the notifier, up to 5% of the import volume of the notified polymer may be lost due to washing of reformulation equipment and 2% is estimated to remain as residues in empty import containers. The washings and residues are expected to be collected and disposed of through an approved waste management facility.

During use, coatings containing the notified polymer are expected to be applied by brush, roller and spray techniques. The notifier indicates that the main release of the notified polymer will most likely be from overspray during use, which is estimated to account for up to 30% of the total import volume. The overspray or spilt material will typically entail collection with adsorbents for disposal as solid wastes to landfill in accordance with local government regulations. Residues containing the notified polymer on brushes and rollers are expected to be rinsed into containers and then allowed to cure before disposal,

as solid wastes, to landfill. Used brushes and rollers and wastes from container residues are expected to be disposed of to landfill in accordance with local government regulations.

Waste water from cleaning processes by DIY users may be incorrectly disposed of to the sewer, drains or ground. Assuming a worst-case scenario where 5% of the total import volume of the notified polymer is released to water system and there is no removal at sewage treatment plants, the predicted environment concentration (PEC) is calculated to be 4.21 µg/L in rivers and 0.42 µg/L in oceans based on the release occurring nationwide 365 days a year [PECriver = 150,000 kg/year × 5% ÷ 365 days ÷ (200.0 L/person/day × 24.386 million population)]. The calculated PEC values and low aquatic hazard indicate that the notified polymer is not expected to reach eco-toxicologically relevant concentrations in the aquatic environment.

The notified polymer will share the fate of the coated article, which is ultimately expected to be disposed of to landfill. In landfill, the notified polymer will be neither bioavailable nor mobile. Furthermore, the notified polymer is not expected to cross biological membranes or bio-accumulate due to its high molecular weight. Testing performed on the notified polymer demonstrated that it was not readily bio-degradable, however it is expected to eventually degrade to form water, oxides of carbon and sodium salts via biotic and abiotic processes.

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

BIBLIOGRAPHY

Boethling, RS & Nabholz VJ (1997) Chapter 10 Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.

Safe Work Australia (2015) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-spray-painting-and-powder-coating.