NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

DMR0608

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/1384 | Clariant (Australia) | DMR0608 | No | < 3 tonnes per | Component of coatings |
| | Pty Ltd | | | annum | and 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 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.

- A copy of the (M)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

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

Secondary Notification

or

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
- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from a component of coatings and 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.

(Material) Safety Data Sheet

The (M)SDS of the notified polymer was provided by the applicant. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants

Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)

Level 3, 3 Acacia Place

296 – 324 Ferntree Gully Road

NOTTING HILL VIC 3168

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

DMR0608

Molecular Weight

Number Average Molecular Weight (Mn) is > 10,000 Da.

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 Viscous liquid 13 °C at 101.3 kPa **Melting Point** Density $1,106 \text{ kg/m}^3 \text{ at } 20 \,^{\circ}\text{C}$ Water Solubility $> 1.0 \times 10^{3} \text{ g/L at } 20 \text{ }^{\circ}\text{C}$ Partition Coefficient (n-octanol/water) -1.6 at 20 - 25 °C

Hydrolysis as a Function of pH $t_{1/2} > 1$ year at 25 °C (pH 4, 7 and 9)

Stable under normal environmental conditions Reactivity

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 | < 3 | < 3 | < 3 | < 3 | < 3 |

Mode of Introduction and Use

The notified polymer will not be manufactured in Australia. It will be imported as a component of liquid or powder pigment formulations at < 30% concentration for reformulation into coatings, paints and printing inks. The finished coatings, inks and paints containing the notified polymer at < 5% will be used by professionals and do-it-yourself (DIY) users and will be applied by brush, roller or spray.

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 | Test Guideline |
|-------------------------------|------------------------------|-----------|----------------|
| | | Observed? | |
| 1. Rat, acute oral | LD50 > 2000 mg/kg bw | no | OECD TG 423 |
| 2. Skin irritation (in vitro) | non-irritating yes | | OECD TG 439 |
| 3. Eye irritation (in vitro) | not corrosive or a severe | no | OECD TG 437 |
| | eye irritant | | |
| 4. Rabbit, eye irritation | non-irritating | yes | OECD TG 405 |
| 6. Guinea pig, Skin | no evidence of sensitisation | yes | OECD TG 406 |
| sensitisation - adjuvant test | | | |
| 7. Genotoxicity - bacterial | non mutagenic | no | OECD TG 471 |
| reverse mutation | _ | | |

In the guinea pig maximisation test (induction concentration: intradermal 3% and topical 100%; challenge concentration: topical 100%) a 20% response was observed, whereas a response of \geq 30% is required for evidence of sensitisation. Evidence of very slight irritation was present in the skin and eye (rabbit) irritation studies.

All results were indicative of low hazard.

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. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

Based on the assessed/assumed low hazard and the assessed use pattern, the risk of the notified polymer to occupational and public health is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment.

The notified polymer will be imported into Australia as a component of pigment formulations for reformulation into coating, painting and printing ink products. Release of the notified polymers at the reformulation site may come from accidental spills or leaks, waste water for reformulation equipment cleaning or disposal of the import container. Spills and leaks are expected to be collected with adsorbing material and be disposed of to landfill in accordance with local government regulations. Residues in the empty drums is expected to share the fate of the containers to be disposed of to landfill.

The finished coating and painting products containing the notified polymer will be applied to substrates by brush, roller or spray. Residues containing the notified polymer on brushes and rollers are expected to be rinsed into containers, and allowed to cure before disposal as solid wastes to landfill. It is estimated by the notifier that up to 1% of the import volume of the notified polymer may enter to

water system from the use of the coating products by DIY users. Release of the notified polymer from printing process is expected to be negligible.

At the end of its useful life, notified polymer used in coating and painting products will share the fate of the coated articles to be disposed of to landfill. Notified polymer used in printing ink is expected to be disposed of to landfill along with the used paper on which it printed or enter water system when used paper is subjected to paper recycling.

In landfill, the notified polymer will be present as cured solids, which will be neither bioavailable nor mobile. Notified polymer entering the water system is expected to be largely removed from water column by partitioning to sludge or sediment during wastewater treatment processes (Boethling and Nabholz, 1997) based on its high molecular weight and non-ionic properties. Therefore, the notified polymer is not expected to be released to surface waters at ecotoxicologically significant concentrations.

The notified polymer is not readily biodegradable (0% biodegradation in 28 days). However, based on its high molecular weight, it is not expected to cross biological membranes, and is therefore unlikely to bioaccumulate. In landfill and water, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

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.

BIBLIOGRAPHY

Boethling RS & Nabholz JV (1997) 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. New York, Van Nostrand Reinhold, pp 187–234.

Safe Work Australia (2015) Code of Practice: Spray Painting and Powder Coating, Safe Work Australia, http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/spray-painting-and-powder-coating.