File No PLC/1177

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in Melio Promul 68.A.

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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

February 2014

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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/1177	Clariant (Australia) Pty Ltd Chemcolour Industries Australia Pty Ltd	Polymer in Melio Promul 68.A.	No	≤ 100 tonnes per annum	Component of leather finishing agent

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 (Material) Safety Data Sheet ((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, 2012) 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 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

- 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.

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 Component of leather finishing agent], 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;
- the method of manufacture of the notified polymer in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the notified polymer on occupational health and safety, public health, or the environment;
- 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 products containing 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)
Brandon Office Park, Building 5, L2,
530-540 Springvale Road, Glen Waverley, VIC 3150

Chemcolour Industries Australia Ltd Pty (ABN 70 125 602 271)
Monash Business Park,
20-22 Gardiner Rd, Notting Hill, VIC 3168

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, use details and import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)
Melio Promul 68.A (product containing the notified polymer).

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	Milky liquid (product)
Melting Point/Glass Transition Temp	Not determined
Density	1,040 kg/m^3 at 20 °C
Water Solubility	Emulsified. Based on its high molecular weight and predominantly hydrophobic structure, the notified polymer is expected to have low water solubility.
Dissociation Constant	Not determined. The notified polymer is a salt and is expected to be ionised under environmental conditions.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

*Physical and Chemical properties are obtained through testing of the aqueous dispersion product Melio Promul 68.A.

5. INTRODUCTION AND USE INFORMATION

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	10-100	10-100	10-100

Use
The notified polymer will not be manufactured in Australia. It will be imported in drums or IBCs as an aqueous dispersion, after which, it will undergo formulation at customer premises for use as a leather finishing agent.

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*
1. Rat, acute oral	LD50 > 5000 mg/kg bw	no	OECD TG 423
3. Rabbit, Acute Dermal Irritation/Corrosion (Analogue)	non-irritating	no	OECD TG 404
4. Rabbit, eye irritation (Analogue)	non-irritating	no	OECD TG 405
5. Genotoxicity - bacterial reverse mutation	non mutagenic	no	OECD TG 471

All results were indicative of low hazard.

If inhalation is suspected to occur during application of products containing the notified polymer, respiratory protection is expected to be used.

The risk of the notified polymer to occupational and public health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

7. ENVIRONMENTAL RISK ASSESSMENT

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 is unlikely apply to the notified polymer and it is therefore not considered to be an over-chelation hazard to algae.

This is supported by environmental endpoints observed in testing conducted on products containing the notified polymer.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	EC50 > 100 mg/L	Not Harmful
Daphnia Toxicity	EC50 = 128 mg/L	Not Harmful
Bacteria Toxicity	IC50> 100 mg/L	Not Harmful

All results for the product are indicative of low hazard for the notified polymer. The notified polymer is not expected to cross biological membranes due to its high molecular weight and low water solubility and is therefore not expected to bioaccumulate.

The notified polymer is used as a component of aqueous dispersions which are applied to, predominantly, cattle hides either by spraying or roller coating. Approximately half of the leather treatment is carried out by roller coating and the remainder by spraying. When applied as a spray, the overspray is collected in a water bath. A total of up to 30 % of leather treatment liquors, containing the notified polymer, is collected as overspray. If one half of introduced polymer is used in spray treatment, then the quantity to be released to waste water treatment systems due to overspray is a maximum of 15 tonnes.

All spray residues collected in the spray chamber water bath are treated in an effluent treatment system. The waste liquids are dosed with acid or alkali to break down emulsions. Solid materials are then collected by flocculation and air flotation, and then filter pressed and partially dried. The notifier has indicated that the removal efficiency of solids is 96%. The solids are collected for disposal by a

licensed waste disposal company. Liquid waste is then discharged to sewer under appropriate licenses from local sewerage authorities.

Under a worst case scenario it will be assumed that 4 % of the notified polymer overspray will be washed into sewer over 70 days each year. Assuming a further 90 % of the notified polymer will be removed via absorption to sludge of a small capacity sewage treatment plant (10 ML/day), the resultant predicted environmental concentration (PEC) in sewage effluent is estimated as 85.7 µg/L [PECriver = 0.857 kg notified polymer/day ÷ 10 ML/day) × 1 (dilution factor)]. The PEC is well below the EC50 for algae of the most toxic anionic polymers (EC50 > 1 mg/L).

Although the notified polymer may be released into waterways, it is unlikely to pose a risk to the aquatic environment given that it is not expected to bioaccumulate nor is it expected to be released at ecotoxicologically relevant concentrations. Therefore, on the basis of the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.