File No PLC/898

February 2010

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Dispersing Agent V4357

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
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Brandon Office Park, Building 5, L2
530-540 Springvale Rd
GLEN WAVERLEY VIC 3150

NOTIFICATION CATEGORY
Polymer of Low Concern

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, Use Details, Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Korea

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Colanyl Yellow 2GXD 130 (product containing the notified polymer at <15% concentration)

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) > 1,000 Da

REACTIVE FUNCTIONAL GROUPS
The notified polymer contains only low concern functional groups.

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:	Yellowish Paste
Melting Point/Glass Transition Temp	50-60°C
Density	1030 kg/m^3
Water Solubility	> 20%, claimed by the notifier. Report not provided. The notified polymer contains a predominant amount of water soluble terminal segments and therefore is considered to be highly water soluble.
Reactivity	Stable under normal environmental conditions. The notified polymer contains hydrolysable functional groups, however, hydrolysis is not expected to occur at the environmental pH range of 4-9.
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	3-10	3-10	3-10	3-10	3-10

Use
The notified polymer will be used as a dispersing agent at up to 15% for pigment preparations that are used for colouration of paints in decorative paint coatings and printing inks.

The majority of dispersing agent (>90%) containing the notified polymer will be used in paint products while approximately <10% products containing the notified polymer will be used for printing inks. Typical substrates for printing inks include corrugated fibreboard for cartons and boxes.

Mode of Introduction and Disposal
The notified polymer will not be manufactured in Australia and will be imported as component of pigment preparations at up to 15% concentration, in 30-50 kg plastic pails with pressure lids or clamp lids.

The pigment preparation containing the notified polymer will be blended by customers with resins and other components of the paint formulations. The pigment preparations containing the notified polymer will be incorporated at the maximum concentration of 10% in paint products, depending on colouration required. The finished paint formulations will contain the notified polymer at the maximum concentration of 1.5%.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Rat, acute oral	LD50 > 2000 mg/kg bw	no	OECD TG 401
Rabbit, skin irritation	slight irritant	yes	OECD TG 404
Rabbit, eye irritation	slight irritant	yes	OECD TG 405
Genotoxicity-bacterial reverse mutation	non mutagenic	no	In-house method

In the skin irritation study, a very slight erythema was observed in one animal at 24 hrs after application, giving a mean score of 0.3 for this animal.

During eye irritation study, the conjunctivae of the animals showed redness in blood vessels at 24 hrs in the first animal, at 24 and 48 hrs in the second animal and at 24 to 72 hrs in the third animal. The mean score was 0.67, 1.0, 0.33 for the first, second and for the third animal, respectively. A very slight swelling of the conjunctiva was observed in one animal at 24 hrs interval. No reaction was observed in the cornea and iris.

All results were indicative of low hazard.

Occupational Health and Safety Risk Assessment
Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is expected to be limited because of the fully/semi automated processes and the engineering controls used and personal protective equipment worn by workers. Exposure is also expected to be limited when used by professional painters due to the implementation of various mitigation measures. Furthermore, once the paint/ink dries, the notified polymer would be trapped in the painted surface or printed paper, and therefore dermal exposure to the notified polymer from contact with the dried paint/ink is not expected.

Overall, the OHS risk presented by the notified polymer is not expected to be unacceptable, based on the low concentration of the notified polymer in the finished paint/ink products and the low intrinsic hazard of the polymer.

Public Health Risk Assessment
The products containing the notified polymer will be sold to the general public. Therefore, there is the potential for dermal, and to a lesser extent oral and ocular exposure, to members of the public during brush and roller paint applications. There is also a potential for public exposure to the notified polymer by coming in contact with the dried painted and printed articles, however it would be trapped in the paint/ink film and would not be bioavailable.

However, considering the low hazard of the notified polymer and the low concentration of the notified polymer in finished paint/ink, and the fact that the notified polymer is bound within the paint/printed polymer system after application, the risk to public health is considered to be low and not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

The notified polymer meets the PLC criteria and can therefore be expected to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified polymer.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Fish Toxicity	LC50 > 220 mg/L	yes[*]	OECD TG 203
Inhibition of Bacterial Growth	IC50 > 1000 mg/L	yes[**]	DIN/EN/ISO 10712 (1996) (DEV-L8)

[*] Some sublethal effects were observed at all the test levels ranging 50 – 220 mg/L.
[**] Negative growth inhibition effects were observed at both test level 500 & 1000 mg/L.

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

Environmental Risk Assessment
The notified polymer will be imported as a component of pigment products in Australia for manufacture of liquid paint products (> 90%) and printing ink products (<10%).

Most of the notified polymer will follow the same fate as the coated substrates and will be disposed of to landfill, where it is bound in the paint or ink matrix. No significant release to the water environment is expected. Based on the study provided by the notifier, the notified polymer is not readily biodegradable but inherently and ultimately biodegradable. Also, the consideration of the high molecular weight indicates that the notified poylmer is not considered to be bioavailable or to have potential for bioaccumulation in the aquatic organisms. In landfill, the notified polymer will undergo slow biotic/abiotic degradation processes, forming water and carbon oxides.

Based on the above considerations and the fact that the notified polymer is not harmful to the aquatic life according to the provided ecotoxicity studies on fish and bacteria in water, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment from the proposed application in Australia.

8. CONCLUSIONS AND RECOMMENDATIONS

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
Based on the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced, in the product Colanyl Yellow 2GXD 130:
  - Avoid contact with skin and eyes

- 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 *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.

Environment

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.

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 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 a component of paint and printing ink, 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 chemical 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 and a product containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.