

File No PLC/758

March 2008

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

FULL PUBLIC REPORT

**2-Propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester, polymer with 2-methylpropyl
2-methyl-2-propenoate**

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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FULL PUBLIC REPORT**2-Propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester, polymer with 2-methylpropyl 2-methyl-2-propenoate****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

Redox Pty Ltd (ABN 92 000 762 345)
2 Swettenham Road
Minto NSW 2566

NOTIFICATION CATEGORY

Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: Polymer Constituents, Residual Monomers/Impurities, and Charge density information

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

None

NOTIFICATION IN OTHER COUNTRIES

US, Canada, China

2. IDENTITY OF CHEMICAL

MARKETING NAME

Dianal BR-115

CHEMICAL NAME

2-Propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester, polymer with 2-methylpropyl 2-methyl-2-propenoate

CAS NUMBER

129698-94-8

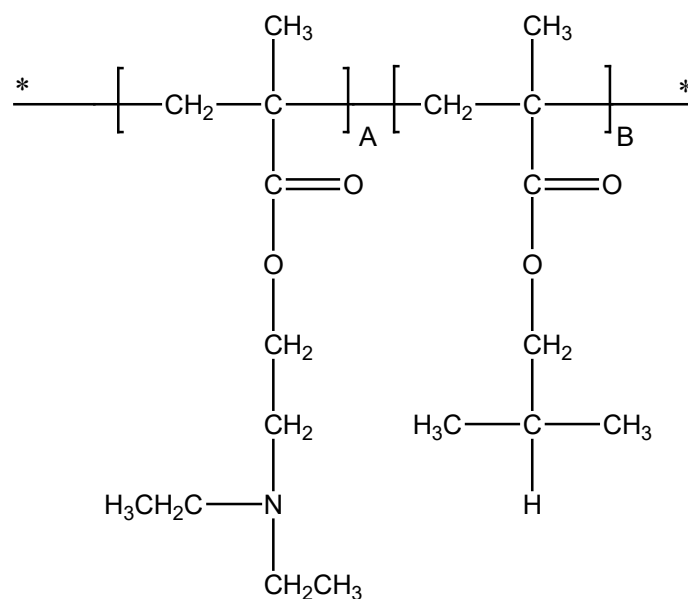
OTHER NAMES

2-Propenoic acid, 2-methyl-, 2-methylpropyl ester, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate
Diethylaminoethyl methacrylate-isobutyl methacrylate copolymer
Polymer of diethylamino methacrylate and isobutyl methacrylate

MOLECULAR FORMULA

$(C_{10}H_{19}NO_2 \cdot C_8H_{14}O_2)_x$

STRUCTURAL FORMULA



MOLECULAR WEIGHT

Number Average Molecular Weight (Mn)	27,353 Da
Weight Average Molecular Weight (Mw)	46,504 Da
Polydispersity Index (Mw/Mn)	1.70
% of Low MW Species < 1000 Da	0 %
% of Low MW Species < 500 Da	0 %

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains potentially cationic amines. However, the functional group equivalent weight of the polymer is greater than 5,000 and therefore the polymer is considered to have a low charge density.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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:	White solid beads
Melting Point	> 160°C
Density	1,100-1,200 kg/m ³
Water Solubility	4.39 mg/L at pH 2 6.61 mg/L at pH 7 8.54 mg/L at pH 9

A sample of the notified polymer was dissolved in water at pH 2, 7 and 9 at a given temperature under agitation up to saturation equilibrium for 24 hours. The amount of the notified polymer dissolved in water was

	determined by total organic content (TOC) as per the OECD Guideline 120.
Dissociation Constant	Based on triethylamine the pKa is expected to be ~ 10.8, therefore the notified polymer is expected to be potentially cationic throughout the environmental pH of 4-9.
Particle Size	100-700 µm (The notifier states that there is no dust associated with the polymer; and there are no particles in the respirable range (< 10 µm) and only a very slight fraction in the inhalable (< 100 µm) range.
Reactivity	Stable under normal environmental conditions.
Degradation Products	None under normal conditions of use. Despite the presence of a potentially hydrolysable functionality, degradation should not occur in the environmental pH range of 4-9. This is supported by limited or no change in dissolved organic carbon (DOC), molecular weight and FT-IR spectra after 1-14 days at pH 1.2, 4, 7 and 9.

5. INTRODUCTION AND USE INFORMATION

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10	10	10	10	10

Use

The notified polymer is intended to be used as a component of conventional (solvent-based) and UV curable ink formulations.

Mode of Introduction and Disposal

The notified polymer will be imported as solid beads by sea from Japan in 25 kg bags. The product will then be transported by road from the Port of Sydney to the notifier's warehouse in Minto NSW for storage. From the notifier's site, the product will be transported by road to one anticipated customer for the formulation of inks.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. The particle size of the notified polymer indicates that the polymer does not pose a significant particulate inhalation hazard. Residual monomers with sensitising properties may be present at ≥ 1%, and accordingly the polymer as marketed is classified as R43 – may cause sensitisation by skin contact.

Occupational Health and Safety Risk Assessment

Transport and Storage

The product containing the notified polymer will be imported in 25 kg bags. Up to 10 workers may be involved in the off-loading, transport and warehousing of the product. These workers are expected to handle the notified polymer less than 10 days/year at 1 hour/day. Dermal, ocular and inhalation exposure to the notified polymer may occur in the event of accidental breaching of the bags.

Ink Formulation

The first step of the ink formulation process involves the blending of the notified polymer with solvents and/or other additives to produce a resin solution. After the resin solutions are produced, the second step of the process is the formulation of the ink itself through the addition of pigments and other minor ingredients. Once the ink is fully formulated, the material will be mixed using a three-roll milling process. After mixing, the final ink formulations will be put into 5 kg or 10 kg containers for distribution to the commercial end user.

The ink formulation process is expected to occur up to 50 days/year (by batch process) with up to 10 workers estimated to be exposed up to 4 hours/day. Dermal, ocular and/or inhalation exposure may occur during the following steps: (a) bag unloading and disposal; (b) vessel loading; (c) intermediate container loading and unloading; (d) three-roll milling operation; (e) final container loading of the ink; and (f) equipment cleaning

operations. Workers will be expected to wear personal protective equipment (PPE) including gloves, goggles and protective clothing. Inhalation exposure is expected to be minimised by use of engineering equipment (e.g. exhaust ventilation).

End Use

The formulated inks will be distributed to 10-20 commercial establishments where the inks will be used in screen-printing operations in the production of posters, signs and other commercial graphics applications. The final ink use is expected to occur at up to 250 days/year with workers exposed up to 4 hours/day. Dermal, ocular and/or inhalation exposure may occur during the following steps: (a) container handling and disposal; (b) ink system loading; and (c) equipment cleaning operations. Workers will be expected to wear adequate PPE to minimise exposure. Inhalation exposure is expected to be minimised by the use of adequate ventilation.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the low exposure to workers and the low intrinsic hazard of the polymer. Use of engineering controls, safe work practices and PPE would reduce exposure and thus reduce the sensitisation risk posed by the residual monomers.

Public Health Risk Assessment

The notified polymer will not be sold to the public except in the form of finished articles. There is potential for extensive dermal exposure to printed articles such as posters, signs and other commercial graphics applications. However, once the ink formulation is applied to the print substrate, the notified polymer is irreversibly cured on to the substrate and is, thus unavailable for exposure. Therefore, the risk to public health will be negligible because the notified polymer is of low hazard and is cured onto the articles.

7. ENVIRONMENTAL IMPLICATIONS

7.1.1 Environmental Release

The notified polymer will be imported from overseas in 25 kg bags. A small amount (<1%) of the notified polymer could be washed off from printing machinery during the normal cleaning process using an organic solvent mix. A licensed disposal contractor for off-site solvent regeneration will deal with this, with the notified polymer being disposed of to landfill.

Residues remaining in the import bags (1-2%) will be disposed of either by incineration or sent to landfill.

The majority of the notified polymer will be bound within the cured coating matrix adhering to printing inks, varnishes and self-adhesive labels. Once the chemical is within a cured coating it is likely to share the fate of the substrate, which might involve recycling or landfill.

7.1.2 Environmental Fate

The notified polymer contains groups that might hydrolyse under severe conditions, but is expected to be stable under normal environmental conditions. Due to its low water solubility, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes. If spilt on land, the notified polymer is expected to bind to soil and become immobilised in the soil layer. If spilt to water, it is not expected to dissolve but rather disperse or settle to sediment. It is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon and nitrogen.

7.2 Environmental Hazard Characterisation

No ecotoxicological data were submitted. While the notified polymer contains potentially cationic functionality the FGEW is > 5000, therefore, low charge density and low aquatic toxicity are expected.

7.3 Environmental Risk Assessment

The notified chemical will be used as a component of conventional and UV curable inks. Once these inks have been cured the notified chemical is expected to remain within the product matrices. Hence, the majority of the notified chemical will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill, recycled or incinerated at the end of their useful lifetime. In landfill it is expected that the notified chemical will remain immobile within the soil. Incineration of the notified chemical will result in the formation of water vapour and oxides of carbon and nitrogen.

During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, toner detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. Sludge generated during the washing process is dried and incinerated or sent to landfill for disposal.

The notified polymer is not likely to present a risk to the environment when it is stored, transported, used, recycled and disposed of in the proposed manner.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment

Under the conditions of the occupational settings described and when used in the proposed manner, the notified polymer is not expected to pose an unreasonable risk to workers and the public.

Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- 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. It is noted that sensitising residual monomers are present in the polymer, and these should be considered in choosing workplace controls.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- 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.

Disposal

- The notified polymer should be disposed to landfill.

Storage

- Store in a cool dry place.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by sweeping up spilled material and placing in a disposal container.

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 ingredient of ink for industrial printing, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased from 10 tonnes per year, or is likely to increase, significantly;
 - if 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 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 notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.