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November 2013

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

**PUBLIC REPORT**

**Ebecryl® 9873**

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 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.

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**

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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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1684	Flint Group Australia Pty Ltd  Allnex Australia Pty Ltd	Ebecryl® 9873	Yes	≤ 40 tonnes per annum	Component of industrial inks

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the table below.

<i>Hazard classification</i>	<i>Hazard statement</i>
Eye Irritation (Category 2)	H319 – Causes serious eye irritation
Skin Irritation (Category 2)	H315 – Causes skin irritation
Skin Sensitisation (Category 1)	H317 – May cause an allergic skin reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

- R36: Irritating to eyes
- R38: Irritating to skin
- R43: May cause sensitisation by skin contact

### Human health risk assessment

Provided that the recommended PPE is used and engineering controls are in place to limit exposure, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

### Environmental risk assessment

On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

### Recommendations

#### REGULATORY CONTROLS

#### Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - Eye Irritation (Category 2): H319 – Causes serious eye irritation
  - Skin Irritation (Category 2): H315 – Causes skin irritation
  - Skin Sensitisation (Category 1): H317 – May cause sensitisation by skin contact

#### Health Surveillance

- As the notified polymer is a skin sensitiser (and the polymer contains hazardous impurities that are skin sensitisers), employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

#### Control Measures

##### Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified polymer:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer :
  - Avoid contact with skin and eyes
  - Avoid inhalation
  - Clean up any spills or soiled personal protective equipment promptly
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Coveralls, impervious gloves and goggles

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.
- 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.

#### Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

#### Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequently 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 chemical 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 chemical, 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(2) of the Act; if
- the function or use of polymer has changed from a component of industrial inks, or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the 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 (M)SDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

## **ASSESSMENT DETAILS**

### **1. APPLICANT AND NOTIFICATION DETAILS**

**APPLICANT(S)**

Flint Group Australia Pty Ltd (ABN: 79 006 659 178)  
25-51 Berends Drive  
DANDENONG SOUTH VIC 3175

Allnex Australia Pty Ltd (ABN: 24 160 397 768)  
Level 12, 680 George Street  
SYDNEY NSW 2000

**NOTIFICATION CATEGORY**

Limited: Synthetic polymer with  $M_n \geq 1000$  Da.

**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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, and import volume.

**VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)**

Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints

**PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)**

None

**NOTIFICATION IN OTHER COUNTRIES**

None

### **2. IDENTITY OF CHEMICAL**

**MARKETING NAME(S)**

Ebecryl® 9873 radiation curing resin (contains  $\leq 85\%$  notified polymer)

**MOLECULAR WEIGHT**

$> 1,000$  Da

**ANALYTICAL DATA**

Reference IR and GPC spectra were provided.

### **3. COMPOSITION**

**DEGREE OF PURITY**

$> 75\%$

**HAZARDOUS IMPURITIES/RESIDUAL MONOMERS**

The notified polymer contains hazardous impurities classified for skin sensitisation that are present at a level above the concentration cut-off.

### **4. PHYSICAL AND CHEMICAL PROPERTIES**

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless to yellow liquid

Property	Value	Data Source/Justification
Freezing Point	Not determined	Expected to be $< 0$ °C
Boiling Point	$> 100$ °C at 101.3 kPa	(M)SDS
Density	1,000 to 1,200 kg/m <sup>3</sup> at 20 °C	(M)SDS
Vapour Pressure	0.133 kPa at 20 °C	(M)SDS
Water Solubility	Not determined	Product containing the notified

Hydrolysis as a Function of pH	Not determined	polymer was observed to be not readily soluble in water. The notified polymer is expected to have low water solubility based on its predominantly hydrophobic structure.
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer contains hydrolysable functionalities. However, significant hydrolysis is not expected to occur under normal environmental conditions (pH 4 – 9).
Adsorption/Desorption	Not determined	Expected to partition from water to n-octanol due to its expected low water solubility.
Dissociation Constant	Not determined	The notified polymer is expected to partition to soil, sediment and sludge and have low mobility in soil based on its expected low water solubility.
Flash Point	> 100 °C at 101.3 kPa (Cleveland open cup)	Does not contain any readily dissociable functionality.
Flammability	Not determined	(M)SDS
Autoignition Temperature	Not determined	Not expected to be flammable based on flash point
Explosive Properties	Not determined	Not expected to undergo autoignition
Oxidising Properties	Not determined	Not expected to be explosive based on the chemical structure.
		Not expected to possess oxidising properties based on lack of structural alerts

## DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

*Reactivity*

The notified polymer is expected to be stable under normal conditions of use. The notified polymer may undergo crosslinking when exposed to intense ultraviolet (UV) light, an electron beam (EB) or initiators.

**Physical hazard classification**

Based on the limited submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

**5. INTRODUCTION AND USE INFORMATION**

## MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will be imported into Australia as a raw material at ≤ 85% concentration or as a component in finished inks at ≤ 20% concentration.

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

Year	1	2	3	4	5
Tonnes	< 40	< 40	< 40	< 40	< 40

## PORT OF ENTRY

Melbourne and Sydney

## IDENTITY OF RECIPIENTS

Allnex Australia Pty Ltd

Flint Group Australia Pty Ltd

## TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a raw material ( $\leq 85\%$  concentration) into Australia in 205 L lined drums for local reformulation into ink products. Alternatively, the notified polymer will be imported as a component ( $\leq 20\%$  concentration) of finished inks in 5 kg bottles or 10 kg plastic buckets. The products containing the notified polymer will be transported from the port of entry by road to the notifier's warehouse facilities.

## USE

The notified polymer will be used as a component ( $\leq 20\%$  concentration) in UV/EB cured lithographic and flexographic printing inks.

## OPERATION DESCRIPTION

Reformulation

At reformulation sites, metering pumps will be used to transfer the notified polymer ( $\leq 85\%$  concentration) from the import containers into a closed blending tank. Therein, the notified polymer will be mixed with other ingredients. The blending tank will be fitted with a high-speed mixer and local exhaust ventilation systems. When blending is complete, a sample will be taken from a sampling port by QA staff for testing. The resulting ink containing the notified polymer ( $\leq 20\%$  concentration) will then be dispensed into 5 kg bottles or 10 kg plastic buckets for supply to end-users.

End-use

The printing processes are largely automated, though some parts require manual assistance. Ink bottles will be manually connected to the printing machines via an inlet and attached to a flexible tube which will supply the ink heads. The inks will be automatically injected into printing machines.

While printers are running, printer operators monitor the operation and keep the substrate feeder stocked and attend to substrate jams. Any residual ink within printing equipment will be removed using cleaning rags and solvents. After printing, the notified polymer will be fixed (UV or EB-cured) with other ink ingredients onto the substrate matrix. Exhaust ventilation will be fitted to the commercial printing machines.

**6. HUMAN HEALTH IMPLICATIONS****6.1. Exposure Assessment****6.1.1. Occupational Exposure**

## CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	4-8	50
Blending operators	8	12-24
Quality control	0.5-6	25
Printer operators	1-2	25
Service technicians	8	200
Wholesale printer supplies	8	200

## EXPOSURE DETAILS

Transport and storage workers may come into contact with the notified polymer ( $\leq 85\%$  concentration) or as a component of ink products ( $\leq 20\%$  concentration) only in the event of accidental rupture of containers.

Reformulation will be largely enclosed and automated; however workers may be exposed (dermal and ocular) to the notified polymer at up to 85% concentration when connecting and disconnecting transfer hoses, during quality control testing and maintenance and cleaning tasks. Dermal and ocular exposure to workers should be mitigated through the use of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles. Inhalation exposure is not expected unless aerosols are formed as the notified polymer is expected to have a low vapour pressure at ambient temperatures. Inhalation exposure to aerosols of the notified polymer should be minimised through the use of local exhaust ventilation and enclosed processes.



The printing process will be largely enclosed and automated; however, workers (printing operators and service technicians) may be exposed (dermal and ocular) to the notified polymer at up to 20% concentration during manual connection of ink bottles to the printing machine, replacement of ink bottles, colour matching processes, quality control operations, and maintenance and service tasks. Inhalation exposure to the notified polymer is not anticipated due to the expected low vapour pressure of the notified polymer, exhaust ventilation and enclosed processes. Dermal and ocular exposure to workers should be mitigated through the use of PPE including protective coveralls, impervious gloves and goggles.

Once the inks are cured and dried, the notified polymer will be bound within a polymer matrix and will not be bioavailable.

### 6.1.2. Public Exposure

The ink products containing the notified polymer (at up to 20% concentration) are only for use in industrial settings and will not be sold to the public. The public may come into contact with the inks containing the notified polymer after application to substrates. However, once the inks are cured and dried, the notified polymer will be reacted and bound within a polymer matrix and will not be bioavailable.

## 6.2. Human Health Effects Assessment

No toxicity data were submitted.

Absorption of the notified polymer across biological membranes (gastrointestinal tract and skin) is unlikely based on the high molecular weight (> 1000 Da) and expected low water solubility. However, the notified polymer contains a high proportion of low molecular weight species (< 500 Da) which may be absorbed.

The notified polymer contains a functional group that has been associated with irritation and skin sensitisation effects (US EPA, 2010). Furthermore, it has also been recommended by the UV/EB acrylate resins sector group in Europe that UV/EB acrylate resins such as the notified polymer should be classified in the absence of data as skin and eye irritants (UV/EB Group, 2011). Indeed the notifier has classified the notified polymer on the MSDS as a skin and eye irritant and a skin sensitiser.

### Health hazard classification

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

<b>Hazard classification</b>	<b>Hazard statement</b>
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- R36: Irritating to eyes
- R38: Irritating to skin
- R43: May cause sensitisation by skin contact

## 6.3. Human Health Risk Characterisation

### 6.3.1. Occupational Health and Safety

The notified polymer is irritating to the skin and eyes, and may cause skin sensitisation.

Reformulation workers may be at risk of irritating and sensitising effects when handling the notified polymer at up to 85% concentration. However, exposure is expected to be limited by the largely automated and enclosed processes and the use of PPE including coveralls, impervious gloves and goggles. Inhalation exposure by workers to the notified polymer is not expected as the vapour pressure of the notified polymer at ambient temperatures is predicted to be low and the largely enclosed processes reduce the potential for exposure to aerosols. Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to the health of reformulation workers is not considered to be unreasonable.

Printer operators will also be at risk of irritating and sensitising effects when handling the formulated inks containing the notified polymer at up to 20% concentration. However, exposure is expected to be limited by the largely automated and enclosed processes, exhaust ventilation and the use of PPE including coveralls, impervious gloves and goggles. Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to the health of printer operators is not considered to be unreasonable.

### **6.3.2. Public Health**

The notified polymer will be used in industrial settings only and will not be sold to the public. The public may come into contact with the printed articles containing the notified polymer. However, once the notified polymer is cured, it will be bound within a polymer matrix and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

## **7. ENVIRONMENTAL IMPLICATIONS**

### **7.1. Environmental Exposure & Fate Assessment**

#### **7.1.1. Environmental Exposure**

##### **RELEASE OF CHEMICAL AT SITE**

The notified polymer will not be manufactured within Australia. However, the notified polymer will be imported to Australia as a raw material for local reformulation of inks. During reformulation, spills and leaks are expected to be collected using suitable absorbent materials and placed in closed containers for disposal to landfill. The notified polymer is not expected to be released to sewers during reformulation. Empty containers are likely to be disposed of to landfill. Residues in the empty containers and waste water from equipment washings are expected to be collected and disposed of to a waste facility.

##### **RELEASE OF CHEMICAL FROM USE**

The majority of the release of the notified polymer to the environment from use will be from ink spills, wash-downs of printing equipment and from disposal of empty containers containing residual ink. The notified polymer is UV-cured (chemically reacted) and it is expected to be stable within an inert matrix on printed substrate once it is cured. A maximum of 3% of ink was estimated by the notifier to be released to sewer from equipment washing and ink colour matching.

##### **RELEASE OF CHEMICAL FROM DISPOSAL**

The notified polymer (up to 80% of the total import volume) in ink is expected to be used for printing on vinyl, canvas and plastic packaging. The notified polymer is expected to share the fate of the printed articles which are expected to be disposed of to landfill. Up to 20% of the total import volume of the notified polymer in ink will be used for paper printing and 50% of the printed papers are expected to be recycled. Hence, 10% of the total import volume of the notified polymer may be released to sewers as residues in recycling waste waters. Empty containers containing residues of the notified polymer (up to 1% of the total import volume) are expected to be disposed of to landfill. Hence, the majority of the total import volume of the notified polymer is expected to be disposed of to landfill with a potential for some release to sewer.

#### **7.1.2. Environmental Fate**

No environmental fate studies were submitted. Approximately half of the paper to which the ink containing the notified polymer is applied to is likely to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. However, the notified polymer is UV/EB cured (chemically reacted) into the ink matrix and is unlikely to be released into the supernatant waters during recycling processes. The majority of the cured notified polymer is anticipated to partition to sludge and sediment. Sludge from treatment plants may be collected for disposal to landfill or used in soil remediation. The notified polymer is not expected to bioaccumulate due to its high molecular weight. Notified polymer applied to substrates will be UV/EB cured (chemically reacted) and is not expected to be bioavailable. The majority of the cured notified polymer is expected to be disposed of to landfill where it is anticipated to degrade by biotic and abiotic processes to form water and oxides of carbon.

#### **7.1.3. Predicted Environmental Concentration (PEC)**

Based on the reported use in printing, it is conservatively assumed that 100% of the total import volume of the notified polymer will be used in paper printing. Using a worst-case scenario, it is assumed that 50% of the paper products containing the notified polymer will be recycled and will be released to the sewer with no removal during recycling or STP processes. As the notified polymer is to be processed at paper recycling facilities located

throughout Australia, it is anticipated that such releases will occur on 260 days into the Australian effluent volume. The resultant estimate for the predicted environmental concentration (PEC) in sewage effluent nationwide is summarised in the table below.

<b><i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i></b>		
Total Annual Import/Manufactured Volume	40,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	20,000	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	76.92	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	17.01	µg/L
PEC - Ocean:	1.70	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m<sup>2</sup>/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m<sup>3</sup>). Using these assumptions, irrigation with a concentration of 17.0 µg/L may potentially result in a soil concentration of approximately 113.4 µg/kg. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 567.0 µg/kg and 1134.0 µg/kg, respectively.

## **7.2. Environmental Effects Assessment**

No ecotoxicity data for the notified polymer were submitted. The notified polymer is a non-ionic polymer which is generally of low concern to the environment. Therefore, the notified polymer has not been formally classified for its acute and long-term hazard under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS, United Nations, 2009).

### **7.2.1. Predicted No-Effect Concentration**

A Predicted No-Effect Concentration (PNEC) has not been calculated as ecotoxicity data for the notified polymer were not available. The notified polymer is not expected to be readily bioavailable and is predicted to have no significant effect on aquatic biota.

## **7.3. Environmental Risk Assessment**

A risk quotient (PEC/PNEC) for the notified polymer was not calculated as a PNEC was not derived. Release of the notified polymer to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. The notified polymer is not expected to be bioaccumulative and is expected to slowly degrade in the environment. Based on the assumed low hazard and the assessed use pattern of the notified polymer, it is not expected to pose an unreasonable risk to the environment.

**APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES****Water Solubility**

Does not appear to be readily soluble in water

Method In-house method

Remarks The appearance of the mixture of water and the test substance (product containing the notified polymer at < 85% concentration) is milky in the solubility test. The test substance (100 mL) forms a dispersion in water (1 L) that separates when the agitation is stopped. It separates into two phases in time, however, a 24-hour cut-off time limit is insufficient to demonstrate full separation to the original two phases. It can be concluded by visual observation that the test substance does not appear to be readily soluble in water.

Test Facility Ruben Cleymans (undated)

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- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- Ruben Cleymans (undated) Water Solubility of Ebecryl 9873 Resin (Unpublished report submitted by the notifier).
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