

July 2015

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

PUBLIC REPORT

Polymer in Ebecryl 80

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

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

**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/1820	Allnex Australia Pty Ltd & Fujifilm Australia Pty Ltd	Polymer in Ebecryl 80	ND*	≤15 tonne/s per annum	Component of UV cured ink

*=Not Determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

Human health risk assessment

Provided that the recommended 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 PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls where possible to minimise occupational exposure to the notified polymer;
 - Enclosed, automated processes
 - Local exhaust ventilation
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to 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
 - Goggles
 - Respiratory protection if inhalation exposure may occur

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 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 or accidental release of the notified polymer should be handled by physical containment, collection and subsequent 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(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;
 - further information becomes available on the sensitisation potential of the notified polymer;
 - the notified polymer is introduced in neat form;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from component of 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)SDSs of the notified polymer and products containing the notified polymer provided by the notifiers were reviewed by NICNAS. The accuracy of the information on the (M)SDSs remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Allnex Australia Pty Ltd (ABN: 24160397768)
Level 12, 680 George Street
Sydney, NSW 2000

Fujifilm Australia Pty Ltd (ABN: 80000064433)
114 Old Pittwater Rd
Brookvale, NSW 2100

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ Da.

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, analytical data, degree of purity, polymer constituents, residual monomers, impurities, 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 except water solubility

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

USA (1992), Canada (2004)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Ebecryl 80 (mixture containing the notified polymer at ~70%)

OTHER NAME

Amine modified polyether tetraacrylate

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference FTIR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

~70%

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 for classification.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear to light amber viscous liquid (Mixture)

Property	Value	Data Source/Justification
Glass Transition Temperature	Not performed	-

Boiling Point	>100°C at 101.3 kPa	(M)SDS*
Density	1,100 g/m ³ at 20°C	(M)SDS*
Vapour Pressure	<1.33 kPa at 25 °C	(M)SDS*
Water Solubility	Not soluble	Measured*
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, significant hydrolysis is not expected in the environmental pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	1.9	Calculated using KOWWIN v1.68 (US EPA, 2011)
Adsorption/Desorption	0.73	Calculated using KOCWIN v2.00 (US EPA, 2011)
Dissociation Constant	Not determined	No dissociable functionality
Flash Point	>100°C at 101 kPa	(M)SDS*
Flammability limits	Not determined	-
Autoignition Temperature	Not determined	Expected to be high based on the flash point*
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* The above mentioned data are for the mixture containing the notified polymer at ~70%.

Reactivity

The notified polymer is intended to react under conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymer cannot be recommended for hazard classification according to the *Globally Harmonised System of 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 either as part of a resin mixture (~70% concentration) or as a component (<20% concentration) of finished inks.

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

Year	1	2	3	4	5
Tonnes	≤15	≤15	≤15	≤15	≤15

PORT OF ENTRY

Melbourne and Sydney

IDENTITY OF RECIPIENTS

Allnex Australia Pty Ltd
Fujifilm Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as part of a resin mixture for reformulation and as a component of finished inks, in 205 L drums and in 5 L plastic bottles respectively. They will be transported from the port of entry by road. The finished ink products are classified as Dangerous Goods (Class 9).

USE

The notified polymer will be used as a component of UV-cured printing ink in commercial large format printers.

OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia. It may be imported as part of a resin mixture (~70% concentration) for reformulation into ink products. The reformulation process will involve the typical blending process. The notified polymer will be transferred to the closed blending tank fitted with high speed stirring paddle by the use of hose and pumping equipment. The blending tank is expected to be in a bunded area and ventilated locally. After testing a sample for quality control, the finished ink will be pumped into 5 L bottles by the use of a filling machine, and distributed to end users.

End-Use

Finished ink products containing the notified polymer (<20% concentration) will be delivered to the end-users (commercial printing companies) from the port of entry or from the reformulation site. Printing inks will be manually transferred to ink tanks from the 5 L plastic bottles, followed by the sealing of the ink tank. Printing will be largely enclosed and automated. While printers are running, print operators will monitor their operation, keep the substrate (eg. vinyl, paper, spun bonded polyethylene) feeders stocked, attend to substrate jams and conduct quality control. Any residual ink within printing equipment will be wiped clean using rags and solvents. These rags and dirty solvents are expected to be disposed of by the printing company through licensed waste disposal contractors.

After printing, the notified polymer will be fixed (UV-cured) with other ink ingredients onto the substrate matrix, and subsequently not expected to be available for release.

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/chemists and technical service	0.5 – 6	25
Printer operators	1-2	25
Service technicians	8	200
Wholesale printer supplies	8	200

EXPOSURE DETAILS

Transport and storage

Exposure to the ink formulations containing the notified polymer is not expected to occur during transport and storage except in the unlikely event of an accident where the packaging is breached.

Reformulation

The reformulation process is expected to be enclosed and automated; however, workers may be exposed to the notified polymer at ~70% concentration during several stages of reformulation including opening containers, connecting/disconnecting hoses and pumping equipment to import containers, sampling for quality control (<20% concentration). Local ventilation, automated and enclosed systems and use of PPE (overalls, gloves, safety glasses, safety boots, and respirator) are expected to minimise the potential for dermal, inhalation and ocular exposure to the notified polymer during the reformulation process.

End-use

Print operators

Print operators are not expected to be exposed to the notified polymer in finished ink products, as the process will be mainly automated. However, dermal and ocular exposure to the notified polymer at <20% may occur during the manual pouring of the ink into printing machines, monitoring the process, keeping the printers stocked with substrate (e.g vinyl, paper) and during maintenance processes and removal of filters. Depending on the printing conditions, inhalation exposure may also occur to vapour or aerosols of the notified polymer during the operation of the printers. However, this is expected to be minimised using local exhaust ventilation installed in areas surrounding the printing machines to remove solvent and any other airborne ink components.

Service technicians

Service technicians may experience dermal exposure to the notified polymer at <20% during printer maintenance but this is expected to be minimised by the use of cotton gloves.

After application to the substrate and curing, the ink containing the notified polymer will be UV-cured (fixed) and hence no longer available for exposure.

6.1.2. Public Exposure

The notified polymer and the end-products containing the notified polymer would be used only in industrial settings. The public may come in contact with the printed substrates (vinyl, paper/board, spun bonded polyethylene) containing the notified polymer. However, once it is UV-cured onto the substrate, it is expected to remain bound in the print matrix and not to be bioavailable.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the products containing the notified polymer at ~70% are summarised in the following table. For full details of these studies, refer to Appendix B. No other toxicological studies are available.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rabbit, skin irritation	Non irritating
Rabbit, skin irritation	Very slightly irritating

Toxicokinetics, metabolism and distribution

Absorption of the notified polymer across biological membranes (gastrointestinal tract and skin) would be limited by the high molecular weight (>1000 Da) and expected low water solubility. However, the notified polymer contains a proportion of low molecular weight species which may be absorbed.

Irritation and sensitization

The notified polymer contains acrylate functional groups that have been associated with irritation and skin sensitisation effects (US EPA, 2010).

The notifier provided two skin irritation studies where the product containing the notified polymer at ~70% was found to be non-irritating to very slightly irritating to skin. On the basis of the available data, the notified polymer is not expected to be a skin irritant.

No data has been provided on eye or respiratory irritation, and the potential for these effects cannot be ruled out. It is noted that a European industry guide (Cefic, 2011) recommends classification of polymeric acrylates for eye irritation in the absence of data (A similar recommendation is made for skin irritation).

No information was provided on the skin sensitisation potential of the notified polymer.

Impurities

The product containing the notified polymer has a hazardous impurity at a concentration of ~30%, which may result in skin sensitisation. This substance is classified as a skin sensitizer and eye irritant by the notifier and by the UV/EB Acrylate Resins Sector Group (Cefic, 2011).

Health hazard classification

Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation**6.3.1. Occupational Health and Safety**

The notified polymer may cause skin sensitisation. It is not expected to be a skin irritant, but may have potential for eye and respiratory irritation.

Exposure and risk of reformulation workers when using the notified polymer at ~70% is expected to be limited by the use of engineering controls (local ventilation, largely automated and enclosed processes) and the use of PPE including coveralls, impervious gloves, safety glasses, safety boots, and respirator if required. Inhalation exposure by workers to the notified polymer would be reduced as the vapour pressure of the notified polymer at ambient temperature is predicted to be low, and the largely enclosed processes reduce the potential for exposure to aerosols.

Printer operators might 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. Exposure of the service technicians to the notified polymer is also expected to be limited by the use of PPE including goggles and gloves.

The controls in place to reduce exposure to the hazardous ingredient present in the product mixture would also reduce exposure to the notified polymer.

Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk posed to occupational health and safety of workers is not considered to be unreasonable.

6.3.2. Public Health

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

ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be blended with other components in Australia to prepare printing inks and coatings. The blending is expected to be largely automated and will occur in enclosed systems. It is estimated that up to 100 kg of the notified polymer is expected to be released from formulation and cleaning of equipment. This is expected to be collected and disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

Inks containing the notified polymer are expected to be printed on paper. Once printing is complete, the notified polymer is expected to be incorporated in an inert matrix and is not expected to be released from the printed paper. The notified polymer will be distributed in 5 L bottles designed to prevent leakage and are not expected to be opened during transport, use, installation or replacement. Therefore, release of ink containing the notified polymer to the environment is not expected under normal conditions. Waste ink from equipment cleaning or spillage is expected to be physically contained with absorbent material and disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Printed waste paper containing the notified polymer is expected to be disposed of to landfill or be subjected for paper recycling. The aqueous wastes from paper recycling are expected to be directed to sewage treatment plants (STPs).

Residual ink or paint products left in empty cartridges or empty containers will most likely be disposed of to landfill or be disposed of in compliance with local regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. Since the notified polymer has a molecular weight greater than 1000 Da and low percentage of low molecular weight species, it is not expected to be able to cross biological

membranes and therefore is not likely to bioaccumulate.

Most of the notified polymer is expected to be immobilised within a polymeric film after printing applications. During paper recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. The notified polymer would be expected to be efficiently removed from waste water in waste water treatment plants through adsorption of the polymer to sludge or by flocculation during paper recycling and water treatment processes. Sludge containing the notified polymer is expected to be disposed of to landfill or applied to soil for remediation of agricultural land. The notified polymer is likely to be bound to soil and sludge due to its cationic functions and is not expected to be mobile in the environment. In landfill or water, the notified polymer is expected to undergo biotic and abiotic degradation, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The notified polymer is used for printing paper as well as other substrates. For the worst case release scenario, it is assumed that 100% of the notified polymer will be used in ink products for paper printing, of which half will be subjected to paper recycling processes. The Predicted Environmental Concentration (PEC) was calculated assuming that the 90% of the notified polymer is removed from influent during sewage treatment processes (STPs) processes by adsorption to sediment and sludge (Boethling & Nabholz, 1997). It was assumed that release of the notified polymer to surface waters occurs from recycling processes over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	15000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	7500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	28.85	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.64	µg/L
PEC - Ocean:	0.06	µg/L

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 57.405 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.383 mg/kg in applied soil. This assumes that degradation of the notified chemical occurs in the soil within 1 year from application. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated biosolids application, the concentration of notified chemical in the applied soil in 5 and 10 years may approximate 1.915 mg/kg and 3.83 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 0.63 µg/L may potentially result in a soil concentration of approximately 0.0042 mg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.021 mg/kg and 0.042 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Ecotoxicological endpoints for the notified polymer were calculated based on structure-activity relationship (SAR) equations assuming a worst case cation charge density for the polymer (Boethling and Nabholz, 1997). The endpoints are summarised in the table below and have been modified by mitigation factors to account for the anticipated binding of the polymer with organic carbon in surface waters.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Acute Toxicity		
Fish Toxicity (96 hour)	LC50 = 58.72 mg/L	Harmful
Daphnia Toxicity (48 hour)	EC50 = 195.274.68 mg/L	Not harmful
Algal Toxicity (96 hour)	EC50 = 22.89 mg/L	Harmful
Chronic Toxicity		
Fish Toxicity	ChV = 3.26 mg/L	Not harmful
Daphnia Toxicity	ChV = 10.85 mg/L	Not harmful
Algae Toxicity	ChV = 6.34 mg/L	Not harmful

Based on the worst case SAR estimations, the notified polymer is potentially harmful to aquatic organisms in environmental waters with typical levels of total organic carbon. The QSAR estimation procedure used here is a standard approach and is considered reliable to provide general indications of the likely environmental effects of the polymer for the purposes of risk assessment. However, this method is not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The estimated hazard data for the notified polymer indicates that, after allowing for the mitigating effects of organic carbon in surface waters, the most sensitive ecotoxicological endpoint is for algae. The endpoint for algae was therefore selected for the calculation of the PNEC below. An assessment factor of 1000 was used as a worst-case calculated acute endpoint was used for determination of the PNEC.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
Algae	22.89	mg/L
Assessment Factor	1000	
PNEC:	22.89	µg/L

7.3. Environmental risk assessment

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	0.64	22.89	0.027
Q - Ocean:	0.06	22.89	0.0027

The risk quotient ($Q = \text{PEC}/\text{PNEC}$) for aquatic exposure is calculated to be < 1 based on the above calculated PEC and PNEC. The Q value of < 1 indicates the notified polymer is not expected to pose an unreasonable risk to the aquatic environment from its proposed use pattern at the proposed maximum import volume.

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

Not soluble

Remarks	In house Method. The notified polymer does not seem to be soluble in water as indicated by the haziness of the solution. A dispersion was formed during the mixing process, but this separated again into two phases during the stabilization period.
Test Facility	Allnex (2014)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – skin

TEST SUBSTANCE	Product containing the notified polymer at ~70% concentration
METHOD	EC Directive 84/449/EEC B.4 Acute Toxicity (Skin Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (1M, 2F)
Vehicle	None
Observation Period	4 days
Type of Dressing	Semi-occlusive.
Remarks -	Three rabbits were each observed for a maximum of four days following a single semi-occlusive application of the test substance (a single dermal dose of 0.5 ml) to intact rabbit skin for four hours.
RESULTS	
Remarks -	There were no signs of toxicity or ill health in any rabbit during the observation period. No dermal response to treatment was observed in any animal throughout the observation period.
CONCLUSION	The product containing the notified polymer is non-irritating to the skin.
TEST FACILITY	Huntingdon Research Centre Ltd. (1992)

B.2. Irritation – skin

TEST SUBSTANCE	Product containing the notified polymer at ~70% concentration
METHOD	EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation)
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (F)
Vehicle	None
Observation Period	4 days
Type of Dressing	Semi-occlusive.
Remarks - Method	Three rabbits were each observed for a maximum of four days following a single semi-occlusive application of the test substance (a single dermal dose of 0.5 ml) to intact rabbit skin for four hours.

RESULTS

<i>Lesion</i>	<i>Mean Score*</i>			<i>Maximum Value</i>	<i>Maximum Duration of Any Effect</i>	<i>Maximum Value at End of Observation Period</i>
	1	2	3			
<i>Erythema</i>	0	0	0	1	< 24 h	0
<i>Oedema</i>	0	0	0	0	N/A	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	There were no signs of toxicity or ill health in any rabbit during the observation period. Very slight erythema was observed in one animal at the first observation (approximately 60 minutes after removal of the dressings). The erythema had resolved by the 24 h observation.
CONCLUSION	The product containing the notified polymer is very slightly irritating to the skin.
TEST FACILITY	Huntingdon Research Centre Ltd. (1998)

BIBLIOGRAPHY

- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NTC (National Transport Commission) (2007) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, <http://www.safeworkaustralia.gov.au/sites/swa/about/publications/pages/managing-risks-of-hazardous-chemicals-in-the-workplace>.
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.
- US EPA (2010), TSCA New Chemicals Program (NCP) Chemical categories, Washington, D.C., <http://www.epa.gov/oppt/newchemicals/pubs/npcchemicalcategories.pdf>
- Cefic(2011) Guide to the Classification and Labelling of Acrylates, 4th edition. European Chemical Industry Council (CEFIC), Brussels, Belgium, UV/EB Acrylate Resin Sector Group, <http://www.cefic.org/Documents/Industry%20sectors/UEVB/Guide-to-the-Classification-and-Labelling-of-UV-EB-Acrylates.pdf>
- Huntingdon Research Centre Ltd. (1992) Skin irritation to the rabbit (920592D/UCB 448/SE, November, 1992). Huntingdon, U.K., Huntingdon Research Centre Ltd (Unpublished report submitted by the notifier).
- Huntingdon Research Centre Ltd. (1998) Skin irritation to the rabbit (UCB 608/970576/SE, January, 1998). Huntingdon, U.K., Huntingdon Research Centre Ltd (Unpublished report submitted by the notifier).