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# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

## PUBLIC REPORT

## **Polymer in Flexocure Force Inks**

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 Sustainability, Environment, Water, Population and Communities.

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/1644	Flint Group Australia Pty Ltd	Polymer in Flexocure Force Inks	ND*	≤1 tonne per annum	Component of flexographic printing
					inks

<sup>\*</sup>ND = not determined

## **CONCLUSIONS AND REGULATORY OBLIGATIONS**

#### **Hazard classification**

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

#### Human health risk assessment

Under the conditions of the occupational settings described, and provided that the recommended controls are adhered to, 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 assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

#### Recommendations

REGULATORY CONTROLS

Health Surveillance

As the notified polymer is a potential skin sensitiser and contains a hazardous impurity/residual
monomer that is classified as a skin sensitiser, 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 engineering controls to minimise occupational exposure to the notified polymer:
  - Use of enclosed, automated processes, where possible
  - Local exhaust ventilation if aerosols are generated.
- 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 eyes and skin
  - 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:
  - impervious gloves
  - goggles
  - protective clothing
  - 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 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 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 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 importation volume exceeds one tonne per annum notified polymer;
  - the polymer is to be formulated and/or manufactured in Australia.

or

- (2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from component of printing inks or is likely to change significantly;
  - 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.

No additional secondary notification conditions are stipulated.

## (Material) Safety Data Sheet

The (M)SDS of a product containing the notified chemical provided by the notifier was 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** 

NOTIFICATION CATEGORY

Limited-small volume: Synthetic polymer with Mn <1000 Da (1 tonne or less per year).

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, spectral data, polymer constituents, additives/adjuvants.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: Hydrolysis as a function of pH, adsorption/desorption, dissociation constant, particle size, flammability, autoignition temperature, explosive and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

#### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Flexocure Force Inks (Products containing notified polymer)

Photocryl DP143 (notified polymer)

MOLECULAR WEIGHT

<1000 Da

ANALYTICAL DATA

Reference IR, DSC, GPC, TGA spectra were provided.

### 3. COMPOSITION

DEGREE OF PURITY 90-94%

Loss of Monomers, Other Reactants, additives, Impurities

No loss of monomers, reactants or impurities is expected under normal conditions of use.

DEGRADATION PRODUCTS

The notified polymer is not expected to degrade under normal conditions of use.

## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Pale yellow liquid

Property	Value	Data Source/Justification
Glass transition temperature	48 °C	Measured
Boiling Point	Did not boil up to 170 °C at 0.13 kPa	Measured. Polymerised at high temperature, with signs of crosslinking from 170 °C.
Density	$1.12 \text{ kg/m}^3 \text{ at } 20 ^{\circ}\text{C}$	(M)SDS
Vapour Pressure	5.56 × 10 <sup>-10</sup> kPa at 25 °C 3.72 × 10 <sup>-9</sup> kPa at 50 °C	Measured

Water Extractability	1.27 × 10 <sup>-8</sup> kPa at 80 °C 0.72% at 40 °C, in deionised water 1.29% at 40 °C, pH 2 0.49% at 40 °C, pH 7 0.33% at 40 °C, pH 9	Measured
Hydrolysis as a Function of pH	Not determined	The notified polymer contains hydrolysable functionalities. However, significant hydrolysis is not expected under environmental conditions due to its limited water solubility.
Partition Coefficient (n-octanol/water)	$\log \text{Pow} > 4.1 \text{ at } 20 ^{\circ}\text{C}$	Estimated
Adsorption/Desorption	Not determined	The notified polymer is expected to adsorb to soil, sediment and sludge and have low mobility in soil based on its low water solubility, potential cationic properties and high n-octonal/water partition coefficient.
Dissociation Constant	Not determined	Due to its limited solubility, the notified polymer may not be readily ionisable although it contains potentially cationic groups.
Flash Point	154 °C at 101.3 kPa	(M)SDS
Flammability limits	Not determined	Not expected to be flammable in air based on high flash point and low vapour pressure
Autoignition Temperature	Not determined	Not expected to undergo autoignition as notified polymer decomposes at >200 °C.
Explosive Properties	Not determined	Notified polymer may polymerise at temperatures >170 °C. DSC showed reaction to be exothermic.
Oxidising Properties	Not determined	The notified polymer contains no functional groups that imply oxidative properties

#### DISCUSSION OF PROPERTIES

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

## Reactivity

The notified polymer is stable in the presence of an inhibitor. The notified polymer is intended to react in enduse. High temperatures, inhibitor depletion, accidental impurities, or exposure to radiation or oxidising agents may cause spontaneous polymerisation reactions generating heat/pressure. Closed containers may rupture or explode during runaway polymerisation.

Based on the 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 chemical will be imported as a component ( $\leq$ 15% concentration) of finished ink products.

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

Year	1	2	3	4	5
Tonnes	1	1	1	1	1

PORT OF ENTRY Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Flint Group

#### TRANSPORTATION AND PACKAGING

The ink products containing the notified polymer at  $\leq 15\%$  concentration will be in sealed plastic or metal containers (5 kg and 20 kg) in cardboard boxes and will be transported from the port of entry by road.

#### Use

The notified polymer will be used as a component of printing inks for flexographic printing onto self-adhesive labels and cartons for use in fast moving consumer goods (e.g. wine/spirit/beer labels and folding cartons).

#### OPERATION DESCRIPTION

No reformulation or repackaging of the notified polymer will occur in Australia.

The containers holding the notified polymer at  $\leq$ 15% concentration will be delivered to the end-users (printing sites) in the same form in which they are imported. Printing inks may be mixed prior to being manually transferred to ink trays. Automated pumps transfer finished inks to the press units. Printing will be largely enclosed and automated. Exhaust ventilation will be fitted to the machines. Generation of aerosols containing the notified polymer is not expected.

Residual ink containing the notified polymer within printing equipment will be removed using cleaning cloths and solvents. Waste materials containing the notified polymer will be disposed through licensed waste disposal contractors.

#### 6. HUMAN HEALTH IMPLICATIONS

## **6.1.** Exposure Assessment

## 6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration	Exposure Frequency
	(hours/day)	(days/year)
Printer Operators	8	220
Technical Staff and Service Technicians	2	100

## EXPOSURE DETAILS

Transport and storage workers are unlikely to be exposed to either of the notified polymer (at <15% concentration) except in the event of an accident.

The printing process will be largely enclosed and automated; however, workers may be exposed to ink products during certain procedures.

Dermal, ocular and perhaps inhalation exposure to the notified polymer may occur during: the ink mixing process (technical); the transfer of ink to ink trays (operators); maintenance and service tasks (service technicians).

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

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 will be minimised by the use of local exhaust ventilation in areas around the printing machines, although generation of aerosols containing the notified polymer is not expected.

#### 6.1.2. Public Exposure

The ink products containing the notified polymer (at  $\leq$ 15% concentration) are intended 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.

Toxicokinetics, metabolism and distribution

The notified polymer is of low number average molecular weight (<1000) and therefore dermal absorption cannot be ruled out.

#### *Irritation and sensitisation*

The notified polymer has acrylate functional groups, which are known to cause irritation and sensitisation (US EPA 2010). It also contains a hazardous impurity/residual monomer at a concentration of 6-10%, which may result in sensitisation by skin contact.

#### Health hazard classification

As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the 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 is of low molecular weight (<1000) and has structural alerts for irritation and sensitisation.

Workers with highest potential for exposure to products containing the notified polymer (at <15% concentration) include printer operators, technical staff and service technicians, when conducting manual processes (e.g. ink transfer, mixing and servicing). Exposure is most likely to occur via the dermal route, although ocular and inhalation exposure to the notified polymer may also occur.

Use of engineering controls to minimise manual handling, safe work practices to avoid contact with spills, and use of PPE would minimise occupational exposure to the notified polymer. Suitable PPE would include impervious gloves, goggles and protective coveralls. If mists or aerosols are expected to be generated, local exhaust ventilation in the areas surrounding the printers and enclosed/automated processes (where possible) would minimise inhalation exposure of workers to the notified polymer. Respiratory protection should be worn by workers if local exhaust ventilation cannot be employed and/or the general ventilation is inadequate. Precautions taken to avoid exposure to the other hazardous ingredients of the product would also reduce exposure to the notified polymer.

The risk to workers is not considered to be unreasonable if such controls are in place.

## 6.3.2. Public Health

The products containing the notified polymer will not be sold to the public. The public may have contact with the dried printed materials. However, once cured, the notified polymer will be reacted and bound within a polymer matrix and will not be bioavailable. Hence, public exposure to the notified polymer is not expected, and the risk to health of the public 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 be imported into Australia as a component of ink in sealed plastic or metal containers. Release of the notified polymer to the environment from manufacturing and reformulation is not expected as these activities will not take place in Australia. Environmental release of the notified polymer is expected to be negligible during importation, storage and transportation as containers are designed to minimise release.

#### RELEASE OF CHEMICAL FROM USE

The notified polymer will be used as a component of printing inks for flexographic printing onto self-adhesive labels and cartons in industry settings. Printing will be largely enclosed and automated. The potential release of the notified polymer to the environment during use may occur due to spills when manually transferring printing inks to ink trays or disposal of liquid wastes from equipment cleaning. These wastes are expected to be collected and contained for proper disposal by trade waste treatment companies, which most likely entails landfill disposal.

## RELEASE OF CHEMICAL FROM DISPOSAL

Following its use as printing ink, the majority of the notified polymer (up to 70% of the annual import volume) is anticipated to share the fate of synthetic–substrate printed articles and be disposed of to landfill. The rest of ink containing the notified polymer (30%) will be used for paper printing. Of the 30% notified polymer applied to paper, half of this amount is expected to be subjected to recycling processes due to the recycling of used paper. Residues in empty containers will comprise up to 5% of the total annual import volume of the notified polymer. Most of the used containers are expected to be recycled and the residual ink will be processed for proper disposal of the notified polymer, which most likely entails disposal to landfill.

#### 7.1.2. Environmental Fate

No environmental fate data were submitted. Notified polymer applied to substrate will be UV/EB cured (chemically reacted) within an inert polymer matrix adhering to the printed articles for its useful life. It is not expected to be bioavailable in this form. Notified polymer in solid waste disposed of to landfill is not likely to be mobile due to its limited water solubility and high n-octanol/water partition coefficient.

Approximately half of the paper to which the ink containing the notified polymer is applied to will 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 adsorb to sludge and sediment (Boethling and Nabholz JV, 1996) with the sludge eventually disposed of to landfill or re-used for soil remediation.

The notified polymer is not expected to be rapidly biodegradable and components of the uncured notified polymer have potential to cross cell membranes due to low molecular weight (<1000 Da). However, low bioaccumulation factors estimated for representative low molecular weight species (BCF < 500) indicate that the notified polymer does not have a potential for bioaccumulation (BCFBAF (v3.01), US EPA 2011). In addition, the majority of the notified polymer is expected to be UV cured within an inert ink matrix and environmental release is expected to be limited. In water, landfill and soil, the notified polymer will eventually degrade via biotic or abiotic processes to form water, oxides of carbon and nitrogen.

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

For a worst case scenario, Predicted Environmental Concentrations (PEC) for ocean and river have been calculated assuming that up to 5% of notified polymer would be released to sewers nationwide as equipment cleaning waste with no removal of the notified polymer in sewage treatment plants. It also assumed that release of the notified polymer occurs over 260 days per annum corresponding to release only on working days.

Predicted Environmental Concentration (PEC) for the Aquatic Compartmen	t	
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of polymer released to sewer	50	kg/year
Days per year where release occurs	260	days/year
Daily polymer release:	0.19	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	
Dilution Factor - Ocean	10	
PEC - River:	0.04	μg/L
PEC - Ocean:	0.004	μg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be  $1000~L/m^2/y$ ear (10~ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10~cm of soil (density  $1500~kg/m^3$ ). Using these assumptions, irrigation with a concentration of  $0.043~\mu g/L$  may potentially result in a soil concentration of approximately  $0.28~\mu g/kg$ . 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  $1.42~\mu g/kg$  and  $2.84~\mu g/kg$ , respectively.

## 7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. The notified polymer contains several types of functional groups which may contribute to its toxicity to aquatic life. Ecotoxicity was estimated for representative low molecular weight components using ECOlogical Structure-Activity Relationships (ECOSAR (v1.00), US EPA 2011) based on these functional group classes. The ecotoxicological endpoints for the notified polymer reported below are based on the results of the most conservative estimations. ECOSAR predictions for higher molecular weight components of the notified polymer indicated that they were not expected to be toxic up to the limit of their water solubility.

The endpoints estimated by ECOSAR for the low molecular weight components may not adequately characterise the toxicity of the notified polymer to aquatic organisms. Ecotoxicological endpoints for the notified polymer, as a whole polymer, were calculated based on Structure Activity Relationships (SARs) equations assuming a worst case cationic charge density for the polymer (Boethling and Nabholz, 1996). The results are also summarised in table below.

Endpoint  ECOSAR predictions for a representative low molecular weight component  Acute	Result	Assessment Conclusion
Fish Toxicity	LC50 (96 h) = 14.49 mg/L*	Predicted not to be harmful to fish up to the limit of its solubility
Daphnia Toxicity Algal Toxicity  Chronic	LC50 (48 h) = 1.96 mg/L EC50 (96 h) = 1.34 mg/L	Potentially toxic to aquatic invertebrates Potentially toxic to algae
Fish Toxicity	$ChV^{**} = 0.282 \text{ mg/L}$	Potentially toxic to fish with long lasting effects

Daphnia Toxicity	$ChV^{**} = 0.051 \text{ mg/L}$	Potentially very toxic to aquatic
		invertebrates with long lasting effects
Algal Toxicity	ChV** = 0.363  mg/L	Potentially toxic to algae with long lasting effects
Cationic polymer SARs		8
<b>P</b> = 3 = = = =		
predictions for the notified		
polymer		
Acute		
Fish Toxicity	LC50 (96 h) = 2.23 mg/L	Potentially toxic fish
Daphnia Toxicity	LC50 (48 h) = 4.11 mg/L	Potentially toxic to aquatic invertebrates
Algal Toxicity	EC50 (96 h) = 0.58 mg/L	Potentially very toxic to algae
Chronic	, ,	
Fish Toxicity	$ChV^{**} = 0.124 \text{ mg/L}$	Potentially toxic to fish with long lasting
,	$\mathcal{E}$	effects
Daphnia Toxicity	$ChV^{**} = 0.294 \text{ mg/L}$	Potentially toxic to aquatic invertebrates
Bupinia Texiory	0.25 mg/2	with long lasting effects
A.1. 1775	C1 1744 0 156 /I	
Algal Toxicity	$ChV^{**} = 0.156 \text{ mg/L}$	Potentially toxic to algae with long
		lasting effects

<sup>\*</sup> Predicted greater than the solubility of the representative component

ECOSAR results demonstrate that only a few of the low molecular weight components of notified polymer are predicted to have potential toxicity to aquatic organisms and therefore, these endpoints are not entirely representative of the ecotoxicity of the whole notified polymer. The cationic polymer SARs endpoints indicate that the notified polymer is potentially very toxic to aquatic organisms. However, these SARS are based on a group of broadly related polymers. Therefore, the ECOSAR and SARs estimations used here are considered acceptable for the purposes of risk assessment. However, they are not considered sufficient to formally classify the acute and long term hazard of the notified polymer to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

## 7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the most conservative endpoint (*Daphnia* ChV) of the notified polymer and an assessment factor of 50. A conservative assessment factor is appropriate, in this case, as although chronic endpoints (ChV = (LOEC × NOEC)<sup>1/2</sup>) for three trophic levels are available, these chronic endpoints are greater than no-observed effect concentrations (NOECs).

Predicted No-Effect Concentration (PNEC) for t	he Aquatic Compartment	
ChV (Invertebrates)	0.051	mg/L
Assessment Factor	50	
PNEC:	1.02	μg/L

## 7.3. Environmental Risk Assessment

Risk Assessment	PEC μg/L	PNEC µg/L	$\boldsymbol{\varrho}$
Q - River:	0.04	1.02	0.042
Q - Ocean:	0.004	1.02	0.004

The risk quotient (Q = PEC/PNEC) for aquatic exposure is calculated to be <1 based on the above calculated PEC and PNEC values. Although the notified polymer has potential to be persistent in the environment and is predicted to have potential toxicity to aquatic organisms, it is not expected to bioaccumulate. On the basis of PEC/PNEC ratio and the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the aquatic environment based on its proposed use and import volume.

<sup>\*\*</sup> ChV = Chronic value =  $(NOEC \times LOEC)^{1/2}$ 

## **APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**

**Boiling Point** >170 °C at 0.13 kPa

Method OECD TG 103 Boiling Point.

Remarks Polymerisation occurred above 170 °C. Notified polymer does not distill at atmospheric

pressure

Test Facility Miwon (2012)

**Vapour Pressure**  $5.56 \times 10^{-10} \text{ kPa at } 25 \text{ }^{\circ}\text{C}$ 

 $3.72\times10^{\text{-9}}$  kPa at 50 °C  $1.27\times10^{\text{-8}}$  kPa at 80 °C

Method OECD TG 104 Vapour Pressure. Remarks Effusion method: Knudsen Cell

Test Facility Miwon (2012)

Water Solubility 0.72% at 40 °C, deionised water,

1.29% at 40 °C, pH 2 0.49% at 40 °C, pH 7 0.33% at 40 °C, pH 9

Method OECD TG 120, Solution/Extraction behaviour of polymer in water.

Remarks Flask method. Water solution/extraction behaviour of the test substance was determined

according to the test guideline above with a deviation from the protocol, whereby the test

was conducted at 40 °C instead of at 20 °C for pH 2 and pH 9, at 37 °C for pH 7.

Test Facility KOPTRI (2012a)

**Partition Coefficient (n-** log Pow > 4.1 at 20 °C

octanol/water)

Method Estimated

Remarks The partition coefficient was estimated based on the solubility of test substance in

n- octanol of >1000 g/L and in deionised water of 0.072 g/L, respectively.

Test Facility KOPTRI (2012b)

## **BIBLIOGRAPHY**

- Boethling RS & Nabholz JV (1996) Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In: Hamilton JD & Sutcliffe R, ed. Ecological Assessment of Polymers; Strategies for product stewardship and regulatory programs. New York, Van Nostrand Reinhold.
- KOPTRI (2012a) Water solubility test under acidic and basic condition of polymer (supplied as product name PHOTOCRYL DP143), (Study No. Koptri-1239-3, June 2012), Seoul, Korea, Korea Polymer Testing & Research Institute (KOPTRI), Miwon Specialty Chemical Co., Ltd, (Unpublished report submitted by the notifier)
- KOPTRI (2012b) Determination of the partition coefficient (n-octanol/water) by estimation method (supplied as product name PHOTOCRYL DP143), (Study No. Koptri-1239-4, June 2012), Seoul, Korea, Korea polymer Testing & Research Institute (KOPTRI), Miwon Specialty Chemical Co., Ltd, (Unpublished report submitted by the notifier)
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3<sup>rd</sup> 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
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3<sup>rd</sup> revised edition. United Nations Economic Commission for Europe (UN/ECE), <a href="http://www.unece.org/trans/danger/publi/ghs/ghs\_rev03/03files\_e.html">http://www.unece.org/trans/danger/publi/ghs/ghs\_rev03/03files\_e.html</a>>.
- US EPA (2010) TSCA New Chemicals Program (NCP) Chemical Categories. Washington. <a href="http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf">http://www.epa.gov/oppt/newchems/pubs/npcchemicalcategories.pdf</a>, accessed March 2013.
- US EPA (2011) Estimation Programs Interface Suite<sup>TM</sup> for Microsoft® Windows, v 4.10. United States Environmental Protection Agency. Washington, DC, USA, <a href="http://www.epa.gov/oppt/exposure/pubs/episuite.htm">http://www.epa.gov/oppt/exposure/pubs/episuite.htm</a> >. Accessed 2013, Jan 11.