File No: LTD/1615

October 2012

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Sartomer CN9167

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:

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

TABLE OF CONTENTS

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/1615	Flint Group Australia Pty Ltd DIC Australia Pty Ltd Brenntag Australia Pty Ltd	Sartomer CN9167	Yes	≤20 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.

Hazard classification	*Hazard statement*
Skin Irritation (Category 2)	H315 – Causes skin irritation
Eye Irritation (Category 2A)	H319 – Causes serious eye 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:

R36/38 Irritating to eyes and skin
R43 May cause sensitisation by skin contact

Human health risk assessment
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:
  - Skin Irritation (Category 2): H315 – Causes skin irritation
  - Eye Irritation (Category 2A): H319 – Causes serious eye irritation
  - Skin Sensitisation (Category 1): H317 – May cause an allergic skin reaction

- The following should be used for products/mixtures containing the notified polymer:
  - Conc. ≥10%: H315, H317, H319

- ≥1% Conc. <10%: H317

Health Surveillance

- As the notified polymer is a skin sensitiser (and the polymer contains a hazardous impurity that is 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 skin sensitisation.

Material Safety Data Sheet

- The MSDS for products containing the notifier polymer should reflect the hazards associated with the notified polymer and the hazardous impurity, if appropriate based on the concentration.

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 (and/or the hazardous impurity):
  - Enclosed, automated processes, where possible
  - Ventilation system including 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 (and/or the hazardous impurity):
  - Avoid contact with skin and eyes
  - Avoid inhalation

- 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 (and/or the hazardous impurity):
  - Coveralls
  - Impervious gloves
  - 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.

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 polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of industrial inks, or is likely to change significantly;
- the amount of polymer being introduced has increased from 20 tonnes per annum, 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 a product 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

DIC Australia Pty Ltd (ABN 12 000 079 550)
42 Sunmore Close
Heatherton VIC 3202

Brenntag Australia Pty Ltd (ABN 84 117 996 595)
262 Highett Road
Highett VIC 3190

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥1000 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, use details 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)
Sartomer CN9167

MOLECULAR WEIGHT
Mn Value >1,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided

3. COMPOSITION

DEGREE OF PURITY <30%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
One hazardous impurity is present at a level above the concentration cut-off for classification. The impurity is present at a concentration of >20% and may result in irritation to the eyes and respiratory system, and sensitisation by skin contact (R36/37, R43 classification provided by the notifier).

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: yellow liquid

Property	Value	Data Source/Justification
Boiling Point	>100 °C	MSDS*
Density	1190 kg/m^3	MSDS*
Vapour Pressure	Not determined	Based on the high molecular weight of the polymer, the vapour pressure is expected to be low.
Water Solubility	1.196×10^{-13} g/L	Calculated** using WSKOW v1.42 (US EPA, 2011)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable groups, however, it is expected to be hydrolytically stable due to its anticipated limited water solubility.
Partition Coefficient (n-octanol/water)	log Kow = 11.62	Calculated** using KOWWIN v1.68 (US EPA, 2011)
Adsorption/Desorption	log Koc = 7.125, 10.713	Calculated** using KOCWIN v2.00 with the Kow and MCI methods respectively (US EPA, 2011)
Dissociation Constant	Not determined	Does not contain readily dissociable functionality
Flash Point	>100 °C (closed cup)	MSDS
Autoignition Temperature	Not determined	Not expected to autoignite under normal conditions of use
Explosive Properties	Not determined	Not expected to be explosive based on the chemical structure
Oxidising Properties	Not determined	Not expected to be oxidising based on the chemical structure

*product containing notified polymer at <35% concentration
**calculated on the lowest molecular weight representative structure of the notified polymer

DISCUSSION OF PROPERTIES

Reactivity

The notified polymer contains functional groups that are intended to react during end-use. The MSDS of the notified polymer advises that high temperatures, inhibitor depletions and exposure to UV radiation and oxidising/reducing agents should be avoided during storage.

Physical hazard classification

Based on the limited 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 POLYMER (100%) OVER NEXT 5 YEARS

The notified polymer will be imported as a component of finished ink products at up to 35% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤20	≤20	≤20	≤20	≤20

PORT OF ENTRY

Sydney or Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Flint Group Australia Pty Ltd
DIC Australia Pty Ltd
International Sales & Marketing Pty Ltd

TRANSPORTATION AND PACKAGING

Inks containing the notified polymer (at up 35%) will be imported in 5 kg bottles or 10 kg buckets and transported by road to end-use sites.

USE

The notified polymer will be used as a component of ultra violet or electron beam cured ink for flexographic and lithographic printing processes.

OPERATION DESCRIPTION

At end-use sites, inks will be colour matched. In general, the printing processes are expected to be mostly automated. The ink bottles will be manually connected to printing machines by attaching transfer lines, which will then inject the ink into the printing machines (separate ink bottles are required for each printing colour). Workers will monitor the printing operations and ensure that the substrate (e.g. paper or vinyl) feeder is stocked and attend to any substrate jams. Any residual ink on printing equipment will be wiped clean using rags and solvents. Exhaust ventilation will be used to remove airborne ink particles. The printed substrates will be subject to ultra-violet or electron beam curing processes.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	4-8	50
Quality control/chemists and technical service	≤6	25
Printer operators	1-2	25

Service technicians	8	200
Wholesale printer supplies	8	200

EXPOSURE DETAILS
During printing operations, exposure is expected to be limited due to the automated nature of the printing processes. Dermal and ocular exposure to the notified polymer (at up to 35% concentration) may occur during colour matching, connecting and replacing transfer hoses, cleaning and maintaining printing equipment and quality control. Inhalation exposure to the notified polymer is not anticipated due to the expected low vapour pressure of the notified polymer. Exposure should be mitigated by the use of exhaust ventilation and personal protective equipment (PPE) - goggles, impervious gloves and coveralls.

Once cured, the notified polymer is not expected to be bioavailable and further dermal contact should not lead to exposure.

6.1.2. Public Exposure
The notified polymer is intended for industrial use only. Therefore, the public may be exposed to the notified polymer (up to 35%) only in the event of a transport accident. While the public may be exposed to the printed articles, the notified polymer will be bound to the substrate and is not expected to be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

Toxicokinetics, metabolism and distribution.
Absorption of the notified polymer across biological membranes (gastrointestinal tract and skin) is unlikely based on the high molecular weight (>1000 Da) and expected high partition coefficient (calculated log Kow = 11.62). However, the polymer contains a high proportion of an impurity and/or low molecular weight species (<500 Da) which may be absorbed.

Irritation and Sensitisation.
The notified polymer contains a functional group that has been associated with irritation and skin sensitisation effects (US EPA, 2010). While the potential for these effects is likely to be limited by the high molecular weight of the notified polymer, they cannot be ruled out, particularly due to the presence of low molecular weight species. The notifier has indicated that the notified polymer should be considered as though it is classified as irritating to eyes and skin and a skin sensitiser.

The notified polymer contains a hazardous impurity at >20% concentration, which may result in skin sensitisation and eye and respiratory irritation.

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 table below.

Hazard classification	*Hazard statement*
Skin Irritation (Category 2)	H315 – Causes skin irritation
Eye Irritation (Category 2A)	H319 – Causes serious eye 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 phrases:

R36/38 Irritating to eyes and skin
R43 May cause sensitisation by skin contact

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the hazards posed by the notified polymer itself and/or the hazardous impurity, skin and eye irritation and skin sensitisation are expected to be the main risks to workers from use of the notified polymer (at up to 35% concentration) during printing operations. While the printing operations are expected to be largely automated (and conducted under exhaust ventilation), dermal and ocular exposure may occur during colour matching, connecting and replacing hoses and during cleaning and maintenance operations. Therefore, exposure of workers to the notified polymer should be avoided during these operations (i.e., through the use of automated processes, exhaust ventilation and PPE). Therefore, when used in the proposed manner and provided that PPE (including coveralls, impervious gloves and goggles) is used by workers to prevent exposure to the notified polymer, the risk to health of workers is not considered to be unreasonable.

6.3.2. Public Health

As the ink products containing the notified polymer (up to 35%) will only be used by professionals, exposure of members of the public to the polymer is not expected except in the unlikely event of an accident. Exposure to the notified polymer is not expected from the dried printed materials, as the notified polymer will not be in a bioavailable form. 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 be imported as a component of industrial printing inks. As manufacturing and reformulation will take place overseas, no release of the notified polymer will occur in Australia from these activities. Spills are expected to be collected using inert solids and disposed of to landfill.

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 residual ink in empty containers. The notified polymer is likely to be stable within an inert matrix on printed substrate once UV-cured. A maximum of 3% of ink was estimated by the notifier to be released to sewer due to the washing of printing equipment and ink colour matching.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be used in inks for printing on vinyl, canvas and plastic packaging and is anticipated to share the fate of the printed articles, which are expected to be disposed of to landfill. A minor amount of ink containing the notified polymer (up to 20% of the annual import volume) will be used for paper printing. Of the 20% import volume applied to paper, half of this amount is expected to be recycled. Residues in empty containers will comprise up to 1% of the annual import volume and are expected to be disposed of to landfill. Formulated ink products will not be released directly to the environment. Hence, it is expected that the total import volume of the notified polymer will predominately be disposed of to landfill with a minor amount potentially reaching the sewer.

7.1.2. Environmental Fate

No data for the environmental fate of the notified polymer were submitted. Notified polymer applied to substrates will be cured and in the cured form is not expected to be mobile, bioavailable or bioaccumulative. The majority of notified polymer is expected to be disposed of to landfill where it will degrade by biotic and abiotic processes to form water and oxides of carbon and nitrogen.

Approximately half of the paper to which the ink containing the notified polymer is applied to will be recycled. During recycling processes, waste paper will be repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. Very little of the notified polymer is expected to partition to the supernatant water which will be released to the sewer, based on the very low predicted water solubility and high predicted adsorption/desorption coefficient (log Koc). Additionally, up to 90% of the notified polymer released to sewer during the recycling process is anticipated to sorb to sludge and sediment (Boethling & Nabholz, 1997), where it is also expected to degrade biotically and abiotically. A proportion of notified polymer may be applied to land when sewage sludge is used for soil remediation on agricultural land or disposed of to landfill. Uncured notified polymer is not expected to bioaccumulate, based on its high

molecular weight and very high predicted n-octanol/water partition coefficient (log Kow), indicating it would be unlikely to cross biological membranes.

7.1.3. Predicted Environmental Concentration (PEC)

Some of the notified polymer will be applied to paper. However, it is expected that this fraction of polymer will be cured on exposure to UV light and will therefore not be bioavailable. Predicted Environmental Concentrations (PECs) for the riverine and marine compartments have been calculated assuming that 3% of the notified polymer will reach the aquatic compartment due to equipment washing and ink colour matching. It was assumed that release of the notified polymer occurs over 260 days per annum, corresponding to release only on working days and that there is no removal during STP processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	20,000	kg/year
Proportion expected to be released to sewer	3%	
Annual quantity of chemical released to sewer	600	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	2.31	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:	0.51	µg/L
PEC - Ocean:	0.051	µg/L

The PEC above was calculated assuming no removal of the notified polymer from STP effluent. However, up to 90% of the notified polymer is anticipated to sorb to sludge and sediment. Therefore, partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 4.59 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/m^3 and a soil-mixing zone of 10 cm, the concentration of the notified chemical may approximate 0.031 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 0.16 mg/kg and 0.31 mg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified polymer were submitted. The notified polymer in its uncured form contains a reactive functional group which may be toxic to aquatic organisms. However, based on its high molecular weight, very high predicted n-octanol/water coefficient (log Kow) and low predicted water solubility, the notified polymer is not expected to be bioavailable and is therefore not likely to exhibit toxicity to aquatic organisms. This is supported by calculations of ecotoxicity endpoints on the lowest molecular weight representative of the notified polymer. Using quantitative structure activity relationships (QSARs) no acute or chronic effects for fish, daphnia or algae were predicted, at saturation of the notified polymer (ECOSAR v1.00, US EPA, 2011).

The ecotoxicity of the notified polymer was predicted using validated QSARs and the notified polymer is considered to be within the domain of the model and selected class. Therefore, the calculated QSAR results are considered reliable for the purposes of classification under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009). Based on the predicted absence of acute and chronic toxicity, the notified polymer is therefore formally not classified for acute or long-term hazard under the GHS.

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its physico-chemical properties, no adverse effects to aquatic organisms are predicted.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) was not determined since a PNEC was not calculated. The majority of the

notified polymer is expected to be disposed of to landfill in a cured form and is therefore not expected to be bioavailable, bioaccumulative or mobile. A minor amount of the notified polymer is expected to be exposed to the aquatic compartment based on the reported use pattern. However, based on its physico-chemical properties, the notified polymer is not anticipated to be bioavailable and hence is unlikely to exhibit toxicity at saturation. The notified polymer is not expected to be bioaccumulative or persistent in the environment, as it is expected to eventually degrade. Therefore, on the basis of its limited aquatic exposure, predicted low toxicity to aquatic organisms and the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

Boethling RS & Nabholz JV (1997) 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, pp 187–234.

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

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/newchems/pubs/npcchemicalcategories.pdf.

US EPA (2011) Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.10. United States Environmental Protection Agency. Washington, DC, USA, <http://www.epa.gov/oppt/exposure/pubs/episuite.htm >. Accessed 2012, Aug 30.