File No: LTD/1425

January 2010

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

# FULL PUBLIC REPORT

## Polymer in Genomer 4215

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:


| | |
|---|---|
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**Director**
**NICNAS**

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### 1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Hewlett Packard Australia Pty Ltd (ABN 74 004 394 763)
353 Burwood Hwy, FOREST HILL VIC 3131

and

CPI Graphics Ltd (ABN 54 004 081 501)
41-45 Mills Road, BRAESIDE VIC 3195

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 Formula, Structural Formula, Polymer Constituents, Molecular Weight, Spectral Data, Concentration and Identity of Impurities, Details of Use, Concentration in Product

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting point/Freezing point, Boiling Point, Density, Vapour Pressure, Water Solubility, Hydrolysis as a Function of pH, Partition Co-efficient, Adsorption/Desorption, Dissociation Constant, Particle Size, Flash Point, Flammability Limits, Autoignition Temperature, Explosive Properties and Reactivity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Genomer 4215

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

### 3. COMPOSITION

DEGREE OF PURITY > 98%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer and the formulated products containing it are in paste and liquid form. Thus the loss of any residual monomer is possible. However, once the polymer has cured, it will be present in a sold ink matrix on the surface of the printed substrate and will be immobile.

DEGRADATION PRODUCTS
The notified polymer is stable under normal use conditions. It may slowly degrade in the environment by biotoic and abotic process to smaller molecules such as oxides of carbon and nitrogen.

## 4. PHYSICAL AND CHEMICAL PROPERTIES

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

| Property | Value | Data Source/Justification |
|---|---|---|
| Transition Temperature | -24°C | Cited in manufacture's technical brochure |
| Boiling Point | > 100°C at 101.3 kPa | Estimated |
| Density | 1140 kg/m$^3$ at 20°C | MSDS |
| Vapour Pressure | Not determined | Expected to be low based on the high molecular weight. |
| Water Solubility | $1 \times 10^{-10}$ g/L at 20°C | Calculated (ACD I-lab). This estimate is consistent with the hydrophobic structure and molecular weight of the notified polymer. |
| Hydrolysis as a Function of pH | Not determined | The notified polymer contains hydrolysable functionality, but hydrolysis is not expected to occur within the environmental pH range of 4-9. |
| Partition Coefficient (n-octanol/water) | Not determined | The notified polymer is expected to partition from water to n-octanol, based on its hydrophobicity. |
| Adsorption/Desorption | Not determined | The notified polymer is expected to bind to organic matter in soil based on its hydrophobicity and reactivity. |
| Dissociation Constant | Not determined | The test could not be preformed due to the expected negligible water solubility. There are no functional groups within the polymer which can undergo dissociation. |
| Particle Size | Not determined | Introduced as a paste. |
| Flash Point | > 100°C at 101.3 kPa | MSDS |
| Autoignition Temperature | Not determined | The notified polymer is not expected to autoignite under normal conditions of use. |
| Explosive Properties | Not determined | Expected to be stable under normal conditions of use. The notified polymer contains no functional groups that would imply explosive properties. |

DISCUSSION OF PROPERTIES

*Reactivity*

The polymer is stable under normal use conditions. It may cross-link when heated to > 50°C or exposed to strong light, particularly UV light. The notified polymer should also be stored away from radical forming initiators, peroxides, highly alkaline materials or reactive metals.

## 5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a component of formulated ink preparations (< 10%).

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

| *Year* | *1* | *2* | *3* | *4* | *5* |
|---|---|---|---|---|---|
| *Tonnes* | 1 | 2 | 3 | 4 | 5 |

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The formulated ink preparations containing the notified polymer in 5 L or 1 L polyethylene containers will be transported by road or rail to the notifier's storage warehouse before being distributed to end user sites.

USE
Additive in printing ink.

OPERATION DESCRIPTION
When used in the printing industry, the ink formulations (typically containing < 10% of the notified polymer) will be transferred directly from the import containers to the printing machine via automated lines. The printing machine will be fully automated and is equipped with UV lamps that cure the product immediately after coating.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

| *Category of Worker* | *Number* | *Exposure Duration (hours/day)* | *Exposure Frequency (days/year)* |
|---|---|---|---|
| Waterside workers | 6 | 2 | 12 |
| Storage & transport personnel | 20 | 4 | 50 |
| Printer operators | 20 | 6 | 200 |
| Service technicians | 5 | 1 | 50 |

EXPOSURE DETAILS
Workers involved in importation, transportation or storage are not expected to be exposed to the imported notified polymer, as they will be handling closed containers. Exposure is possible in the event of an accident where the packaging is breached.

Printer operators and service technicians will come in contact with the notified polymer (at < 10%) during certain processes, including printer maintenance, connecting and disconnecting bottles and handling the printed substrate once the ink has been fully cured. The most likely route of exposure will be dermal. Inhalation exposure is unlikely due to the low volatility of the notified polymer. Oral exposure is not expected. Exposure will be limited by the expected use of local exhaust ventilation in areas of printing machines and workers wearing personal protection equipment, including impermeable gloves.

After application to substrate, the ink containing the notified polymer is cured into an inert paper or film matrix and exposure is not expected.

#### 6.1.2. Public exposure
The ink product containing the notified polymer will only be used for commercial purposes. The public will not be exposed to the concentrated product except in the event of accidental spillage during road transportation. The general public is only expected to come into contact with the notified polymer after the ink or coating formulation is cured to the substrate. Therefore, public exposure is not expected.

### 6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix A.

| *Endpoint* | *Result and Assessment Conclusion* |
|---|---|
| Rabbit, skin irritation | slightly irritating |
| Rabbit, eye irritation | slightly irritating |

*Toxicokinetics and Distribution*
Based on the high molecular weight (Mn > 1000), low water solubility and expected high lipophilicity, absorption across biological membranes is expected to be low. Systemic toxicity after dermal exposure to the notified polymer is therefore expected to be low.

*Irritation*
The notified polymer was slightly irritating to skin and eyes.

*Sensitisation*
The notified polymer contains a pendant acrylate group that is a structural alert for sensitisation (US EPA 2002). Given the notified polymer contains a high percentage of low molecular weight species (< 1000Da) it may possess some sensitising properties.

***Health hazard classification***
Based on a structural alert and high percentage of low molecular weight species, the notified polymer may have skin sensitisation properties. However, the available information is not sufficient to classify the notified polymer as a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

### 6.3. Human health risk characterisation

#### 6.3.1. Occupational health and safety
Based on the available toxicological data, the notified polymer was slightly irritating to skin and eyes. The notified polymer may cause sensitisation.

The notified polymer will be imported as a component of the ink formulations (typically containing < 10% of the notified polymer), which will be transferred directly from the import containers to the printing machine via automated lines.

Considering the likely low exposure of the workers at each step of use, the risk of adverse effects for workers involved in transport, storage, printing and servicing is low.

However, there is a possibility of accidental oral and/or dermal exposure to the notified polymer during maintenance and servicing of the printing equipment. Expected use of personal protection equipment by workers should minimise exposure during these activities.

Once deposited onto the paper, the notified polymer is expected to remain bound to the paper or the cured print matrix. Therefore exposure is not expected. The risk to workers from exposure to the notified polymer is considered to be low.

#### 6.3.2. Public health
As no exposure is expected from the cured printed material, the risk to the public from the use of the notified polymer is low.

## 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 or reformulated within Australia. Therefore, release may only occur in an accident during transportation and handling of the imported formulated products, and as such is not expected to be significant. Spilt material is expected to be physically contained, collected and subsequently disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

*Residual within containers*

The notifier claims that only a small proportion, estimated at ≤ 5% of the total import volume, will remain as residual within the import 1 – 5 L containers. It is claimed by the notifier that residual notified polymer within import containers will be cured by UV light before disposal to landfill.

*Applied notified polymer*

The formulated products containing the notified polymer will be applied to substrate using industrial inkjet printers. The applied notified polymer is expected to chemically react with other ingredients of the ink, in the presence of UV light, to form an inert polymer matrix on the substrate. Significant quantities of unreacted notified polymer are not expected to remain, however these should remain entrapped within the stable polymer matrix and share the fate of the substrate to which it has been applied.

*Release from equipment cleaning during maintenance*

A very small proportion, estimated at ≤ 1% of the total import volume, may be released from equipment cleaning during maintenance operations on printing equipment. While this may be disposed of to sewer, given the expected very low water solubility, it is expected that any notified polymer released to sewer would partition to sludge and be removed in STPs. This partitioning and removal would be enhanced on exposure to light (especially UV) which would promote cross-linking, further lowering the solubility in water.

RELEASE OF POLYMER FROM DISPOSAL

As a worst case, it is assumed that up to 50% of the substrate may be recycled, with the remainder being disposed of to landfill at the end of its useful life.

Unreacted notified polymer associated with substrate that has been sent for recycling, may theoretically be released to sewer. However, as discussed above, the majority of this is expected to adsorb to sludge and sediment and be subsequently disposed of to landfill. Significant release to the natural aquatic environment is therefore not anticipated, especially as the majority will be applied to vinyl substrates, rather than paper, and thus a Predicted Environmental Concentration (PEC) has not been calculated.

### 7.1.2 Environmental fate

No environmental fate data were submitted. Notified polymer that is disposed of to landfill is expected to remain associated with the substrate to which it has been applied in the form of an inert cross-linked polymer matrix. Overtime the polymer matrix is expected to degrade via biotic and abiotic processes to form predominantly simple organic and inorganic compounds.

## 7.2. Environmental effects assessment

No ecotoxicity data were submitted. Given the expected very low water solubility and high molecular weight, the notified polymer is not expected to cross biological membranes or bioaccumulate.

## 7.3. Environmental risk assessment

The notified polymer is unlikely to be released into aquatic ecosystems in environmentally significant concentrations based on the intended use pattern and the potential for removal of the polymer from wastewater streams by physical processes, especially adsorption to solids. Thus, there is a low risk to the environment based on the lack of pathways for aquatic exposure to the polymer.

# 8. CONCLUSIONS AND REGULATORY OBLIGATIONS

**Hazard classification**

Based on the limited information provided the notified polymer cannot be classified as a hazardous substance according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

**Human health risk assessment**
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

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

**Environmental risk assessment**
On the basis of the reported use pattern, the notified polymer is not considered to pose an unacceptable risk to the environment.

**Recommendations**

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer in ink preparations:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during connecting ink containers to equipment and maintenance activities:
  - Protective gloves
  - Long-sleeved protective clothing

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed 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 chemical 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 the chemical has changed from additive in printing ink, or is likely to change significantly;
- the amount of chemical being introduced has increased from 5 tonne per year, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical 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 MSDS of the products containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

# APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

## A.1. Irritation – skin

TEST SUBSTANCE: Notified polymer

METHOD: Based on Consumer Product Safety Commission of the U.S.A. in the Code of Federal Regulations, Title 16, Section 1500.41.

| | |
|---|---|
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 6 |
| Vehicle | None |
| Observation Period | 72 hours |
| Type of Dressing | Occlusive |
| Remarks - Method | 0.5 mL of test substance was applied under a gauze pad to one intact and one abraded skin site on each animal. A skin area of 10 $cm^2$ was clipped and an area of 2.5 $cm^2$ within this area was abraded. A second area was left intact (not abraded).<br>Treatment sites were occluded using "Elastoplast" backed with "Sleek" plaster for approximately 24 hours. At the end of the exposure period the occlusive dressing and gauze pads were removed and the treatment sites wiped to remove any residual test substance.<br>This test was not done under Good Laboratory Practice (GLP). |

RESULTS

| *Lesion* | Mean Score* | | Maximum Value | | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|---|
| | Intact | Abraded | Intact | Abraded | | |
| *Erythema/Eschar* | 0.08 | 0.17 | 1 | 1 | < 72 hours | 0 |
| *Oedema* | 0 | 0 | 0 | 0 | - | 0 |

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

Remarks - Results: Only very slight erythema was observed in one intact and two abraded sites at the 24 hours reading. These reactions had resolved completely by the 72 hours reading.

Four animals showed no observable response to treatment throughout the 72 hours observation period.

CONCLUSION: The notified polymer is slightly irritating to the skin.

TEST FACILITY: Huntingdon Research Centre Ltd (1986)

## A.2. Irritation – eye

TEST SUBSTANCE: Notified polymer

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

| | |
|---|---|
| Species/Strain | Rabbit/New Zealand White |
| Number of Animals | 1 M, 2 F |
| Observation Period | 72 hours |
| Remarks - Method | The pH of the test substance was not assessable.<br>Conjunctiva: discharge was not recorded. |

RESULTS

| *Lesion* | *Mean Score* Animal No.* | | | *Maximum Value* | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | | | |
| *Conjunctiva: redness* | 0 | 0 | 0.3 | 1 | < 48 hours | 0 |
| *Conjunctiva: chemosis* | 0 | 0 | 0.3 | 1 | < 48 hours | 0 |
| *Corneal opacity* | 0 | 0 | 0 | 0 | - | 0 |
| *Iridial inflammation* | 0 | 0 | 0 | 0 | - | 0 |

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

Remarks - Results

No clinical signs of toxicity were observed in the animals during the test and observation period, and no mortality occurred. The body weights of all rabbits were considered to be within the normal range of variability.

Remnants of test article were seen in the form of colouration around the eye and/or lids of all animals at all readings.

No corrosion of the cornea was seen at any observation time.

Slightly reddened conjunctivae was observed in the male and one female animal 1 hour after application and persisted until 24 hours in the female only. A slight swelling conjunctivae was also observed in the same female at 24 hours.

CONCLUSION

The notified polymer is slightly irritating to the eye.

TEST FACILITY

RCC Ltd (1999)

## BIBLIOGRAPHY

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