File No PLC/741

10 January 2008

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Tuftone R-4057

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 and Water Resources.

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)
Kao (Australia) Marketing Pty Limited (ABN 59 054 708 299)
1-5 Commercial Road
Kingsgrove, NSW 2208

NOTIFICATION CATEGORY
Polymer of Low Concern

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, Polymer Constituents, Residual Monomers, Use Details and Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Tuftone FK-1 (Product containing the notified polymer)

MOLECULAR WEIGHT (MW)
Number Average Molecular Weight (Mn) >1000 Da

Reactive Functional Groups
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	Criterion met
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Pale yellow odourless powder

Melting Point/Glass Transition Temp	100-115°C
Density	1100 kg/m^3 at 20°C
Water Solubility	< 1 mg/L at 25°C. A 1 g of the sample and 100 ml of water were placed in a flask and was slowly shaken in a water bath at 25°C for 24 hours. The insoluble components were separated from the solution by filtration using a membrane filter (0.45 µm). The total organic carbon (TOC) measuring of the filtrate was performed.
Dissociation Constant	The polymer contains three types of anionic groups, with resulting pKa values in the range of 1.0 – 5.0.
Particle Size	16.5% of the notified polymer is less than 150 µm.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use. While the notified polymer contains hydrolysable functionality, this is not expected to occur in the environmental pH range of 4-9.

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	1	2	3	4	5
Tonnes	1-3	3-10	10-15	10-15	10-15

Use
The notified polymer is used as a component of toner cartridges and developers for industrial printing machines.

The developer will be supplied in 3000g development unit and will be injected into the printer when the indicator light flashes showing that developer is running out. The development unit is opened and inserted into the inlet, which automatically feeds the developer into the printer. Trained service technicians will handle both products containing the notified polymer.

Mode of Introduction and Disposal
The notified polymer will not be manufactured or reformulated in Australia.
The notified polymer will be imported through the port of Sydney as a component of sealed toner cartridges (300 g capacity) at a concentration of < 10%. The notified polymer will also be imported in as developer in 3000 g development unit at a concentration of < 1%. Transportation of the products containing the notified polymer throughout Australia will primarily be by road.

6. HUMAN HEALTH IMPLICATIONS

Hazard Characterisation
No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

Occupational Health and Safety Risk Assessment

Number and Category of Workers			
Category of Worker	*Number*	*Exposure Duration Hours/Day*	*Exposure Frequency(Days/Year)*
Transport and storage	10-20	4-8	200
Service Technicians	200	8	200
Printer operators	>1000	0.1	5
Wholesale printer supplies	>1000	8	200

Transport and warehousing
Transportation and warehouse workers 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.

Wholesale Workers
These workers will be involved in opening cardboard cartons, removing the toner cartridges and development units containing the developer (Both the toner cartridge and developer are contained within an outer cardboard box) and stacking the individual boxes onto shelves. These workers will not have any contact with the toner cartridge or developer and minimal exposure to the notified polymer.

Service technicians
Service technicians will come in contact with the sealed toner cartridges and developers during printer maintenance. Any empty or defective cartridges will be replaced with new ones. No attempt will be made to repair or refill the cartridges. Printers requiring developer will be fed developer through a dedicated inlet in the front of the printing machine. The most likely route of exposure is dermal. Inhalation exposure is unlikely as the notified polymer is of high molecular weight and is expected to have negligible vapour pressure and the formation of dust is unlikely due to the sealed nature of the cartridges and the design of the inlet for the developer. Similarly accidental oral exposure is not expected to be significant. Printer maintenance personnel often wear cotton disposable gloves. Worker exposure to the toner and developer is minimized further by the use of the replacement procedures recommended by the manufacturer.

Printer operators
Printer operators are not expected to be exposed to the notified polymer. Exposure will also be limited because of the good general ventilation in areas of printing machines.

After application to paper substrate and once dried, the toner and developer containing the notified polymer is cured into an inert matrix and hence unavailable to exposure.

Public Health Risk Assessment
The notified polymer will not be sold to the public. The public may be exposed in the unlikely event of a transport accident where the transport containers are breached and product is spilled. The public will also come into contact with final product (e.g. printed paper) coated with the toner and developer containing the notified polymer. However, at this stage the notified polymer will be trapped within the paper matrix and not be bioavailable.

7. ENVIRONMENTAL IMPLICATIONS

Hazard Characterisation
No ecotoxicological data were submitted. Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is overchelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. This is unlikely to apply to the notified polymer. However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups.

Environmental Risk Assessment
The notified polymer or the printing components containing it will not be manufactured in Australia. The notified polymer will only be imported in sealed purpose built 300 - 3000 g toner cartridges and developer units. The release of the notified polymer will be low and diffuse. The environmental safety controls and use pattern for the notified polymer would indicate a limited potential for its release into the environment. Aquatic release of the formulation containing the notified polymer is considered unlikely and after drying the notified polymer is likely to be stable within an inert matrix on printed-paper products.

Emptied toner cartridges containing a residue of notified polymer will be sent to landfill for disposal. In a landfill, the notified polymer is expected to be immobile, and eventually it will degrade through biotic and abiotic processes, and consequently, should not pose a significant exposure hazard to the environment.

Empty development units containing the developer will be disposed off to landfill. The residual in the imported development units are expected to contain up to 0.5% of the notified polymer. Some losses of the polymer may occur as a result of incidental spills during loading of printer with developer, however the small size of the containers will limit the size of spill. It is estimated that 0.5% of notified polymer may be released from spills. Spills are collected by a vacuum cleaner. Collected spilt material will be disposed off to landfill.

In the end use process it would be expected that the notified polymer will be bound to the paper, with the fate of the notified polymer dictated by paper disposal trends. Where recycling does not occur the notified chemical will be disposed of in landfills where it is expected to remain bound to the treated paper.

Paper recycling is carried out in paper mills, where it is likely that at least primary sedimentation occurs, and with some facilities also having biological treatment facilities. Therefore, in these facilities it is expected the notified chemical to partially partition into sludge under the usual waste treatment pH, and eventually be disposed of in landfill with other waste sludge. However, due to the expected water solubility, limited amounts will stay in the water column. It is anticipated that prolonged residence in an active landfill will eventually degrade the notified chemical contained in sludge or in papers disposed of directly through normal garbage.

The relatively high molecular weight indicates that the polymer is unlikely to cross biological membranes and therefore, should not bioconcentrate. Given the diffuse release pattern, the notified polymer is not expected to pose an unacceptable risk to the aquatic environment.

8. CONCLUSIONS AND RECOMMENDATIONS

Human health risk assessment
Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

When used in the proposed manner the risk to the public is considered to be acceptable.

Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

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

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges and developer units containing the notified polymer and during routine maintenance and repairs.

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

- If products and mixtures containing the notified polymer 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 and/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(1) of the Act; if
  - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of toner cartridges and developers for industrial printing machines, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 15 tonnes, or is likely to increase, significantly;
  - if 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 a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.