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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Acrybase FCA-N3

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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FULL PUBLIC REPORT

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cintox Pty Ltd (ABN 85 096 197 885)
121 Carlton Crescent
Summer Hill NSW 2130

NOTIFICATION CATEGORY
Limited: Synthetic polymer with NAMW ≥ 1000.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical identity (Chemical name, other names, CAS. Number, Molecular Formula, Structural Formula. Molecular weight, Spectral Data), Composition (Purity, identity of toxic or hazardous impurities, % weight of toxic or hazardous impurities, non-hazardous impurities), Specific use details, Import volume

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

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA PMN 2004

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Acrybase FCA-N3

MOLECULAR WEIGHT Mn > 1000

ANALYTICAL DATA
Reference IR, and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities and residual monomers are present at below the relevant cut offs for classification of the notified polymer as a hazardous substance.

DEGRADATION PRODUCTS
The notified polymer is stable under normal use conditions. Carbon monoxide, carbon dioxide and other possible toxic gases may be produced in the case of fire.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The notified polymer is a solid. While the loss of monomers is possible, it is unlikely to occur, as the monomers would be bound within the solid matrix.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Pale yellow/brown powder

Property	Value	Data Source/Justification
Melting Point	Not determined	The notified polymer is a cross-linked solid and is expected to decompose before a melting point is reached.
Density	Approximately 1100 kg/m^3 at 25°C	MSDS
Vapour Pressure	Not determined	Based on the high molecular weight the notified polymer is expected to have a low vapour pressure.
Water Solubility	1.5 mg/L at 20°C	Measured
Hydrolysis as a Function of pH	Contains a functional group which has potential to hydrolyse in extreme conditions. However, no evidence of hydrolysis was reported when tested at pH 1.2-9.0.	Measured
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer has low water solubility and would be expected to partition to the organic phase.
Adsorption/Desorption	Not determined	The notified polymer has low water solubility and would be expected to adsorb to organic matter in soil.
Dissociation Constant	Not determined	The notified polymer has low water solubility and the determination of the dissociation constant is not required. The notified polymer contains functional groups which are expected to have pKa values between 10-12.
Particle Size	Inhalable fraction (<100 μm): 92.4% Respirable fraction (<10 μm): 5.9% Mean diameter - 32.91 μm	Measured
Flammability limits	Not determined	Based on the expected low volatility it is not expected to form a flammable air/vapour mixture.
Explosive Properties	Not expected to be explosive	The notified polymer does not contain any structural alerts for explosivity.

Discussion of Observed Effects

For full details of the physical-chemical properties tests please refer to Appendix A.

Reactivity

The notified polymer is stated to be stable under normal use conditions and will not react further during use. The stability of the notified polymer in water was tested under various pH conditions for 24 hours (pH 1.2) or 2 weeks (ph 4.0, pH 7.0, pH 9.0). No significant differences in sample weight, IR spectra or molecular weight distribution were observed.

Dangerous Goods classification

Based on the available physico-chemical properties the notified polymer is not classified as a Dangerous Good according to the Australian Dangerous Goods Code (FORS, 1998).

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will not be manufactured in Australia. It will be imported as a component of finished toner for photocopiers and printers at a concentration of < 5% in purpose-built cartridges or plastic bottles.

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

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

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
The identity of customers is unknown at present.

TRANSPORTATION AND PACKAGING
The notified polymer will be imported as a component in a finished photocopier/printer toner. It will be transported by ship in containers. Individual bottles (1000 g capacity) or cartridges (800 g capacity) will be packed in sturdy cardboard boxes and would normally be transported by road.

USE
Acrybase FCA-N3 will be used as a component in photocopier and printer toner at concentrations < 5%.

OPERATION DESCRIPTION
The local operations will involve transport, warehousing, distribution, and use. No reformulation or repackaging of the imported product containing the notified chemical occurs in Australia. Sealed cartridges or bottles containing the notified chemical will be handled by service technicians or office workers or the public, who will replace spent cartridges in the photocopiers/printers as necessary. Office workers and the public will also use the printers for varied printing work. The cartridges and bottles containing the notified chemical are designed for a single use, and it is not intended that they be refilled and re-used.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure assessment

6.1.1. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	20	8 hours/day	230 days/year
Service technicians (estimate)	50	8 hours/day	230 days/year
Office workers	1000	5 to 10 minutes/day	10 days/year

Exposure Details

Exposure to workers during transport and storage is possible only in the event of an accident where the containers are damaged.

Dermal and inhalation exposure of printer users and service technicians to toner containing < 5% of the notified polymer is possible but unlikely as the notified polymer is sealed within the toner cartridge and is only subject to slow, controlled release from the purpose built cartridge during use. The toner bottle containing the notified polymer is attached to a fitting inside the machine and the toner is fed directly into the printer/copier through a dedicated inlet through an automated process. Exposure to the notified polymer due to spills may occur, but would be limited due to the size of plastic bottle (1L) and the low concentration of the notified polymer present (< 5%). It is possible that impurities and low molecular weight species could be released from the polymer if the printing process generates heat.

Dermal or inhalation exposure of workers to the notified chemical could occur during replacement of cartridges/bottles in the printers/photocopiers. However, this will be minimized as procedures for correct replacement of cartridges are contained in the manufacturer's literature. Also, service technicians will normally be trained adequately for the tasks they perform.

Generally, the printing equipment will be used in well ventilated areas. Service technicians will wear dust mask if ventilation is poor and dust exposure is likely.

Once released onto the paper, the notified polymer is expected to remain bound to the paper in the cured print matrix and will not be bioawailable.

6.1.2. Public exposure

Similar to office workers, the public may intermittently be exposed to the notified chemical when replacing spent cartridges and during use of printers. However, as it is expected that the public will be using the printer less frequently than workers, exposure is also expected to be lower.

6.2. Human health effects assessment

No toxicity data were submitted.

Based on the high molecular weight (Mn > 1000) and low percentage of low molecular weight species (< 1%) absorption across biological membranes is expected to be very low. Systemic toxicity after dermal exposure to the notified polymer is therefore expected to be low.

The particle size distribution of the notified polymer indicates that the mass median diameter is 32.91 μm, with only 5.9% of the particles having a diameter less than 10 μm (respirable range). Therefore, the risk of significant respiration of the polymer powder into the lungs resulting in lung overloading is low. However, the notified polymer is a water insoluble polymer with relatively high molecular weight. According to US EPA there is a concern of lung overloading for insoluble polymers with very high MW.

Similar resins are known to be skin sensitisers, in some cases, and the effect is believed to be related to the presence of impurities and low molecular weight species. In the case of the notified polymer low molecular weight species and residual monomers that may be hazardous (toxic and/or skin sensitisers) are present at very low concentrations below the corresponding hazard cut offs. The notified polymer was stable when tested under various pH conditions suggesting that no significant release of toxic monomers is likely during normal conditions of use.

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified chemical will be imported as a component of the finished toner for photocopiers and printers at a concentration of <5%. The toner will be imported in a purpose-built cartridge or in a plastic bottle. No toxicological studies were provided for the notified chemical.

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

However, because there is a possibility of inhalation exposure to the notified chemical during maintenance and servicing of the printing equipment and the risk of adverse effects related to lung overloading cannot be excluded. Therefore, the level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m^3.

US OSHA recommends that this type of polymers must be handled with adequate ventilation, as traces of free residual monomers may be present. These may be released at higher temperatures of use in printing. However, exposure would be limited by the low quantity used at one time.

Once deposited onto the paper, the notified polymer is expected to remain bound to the paper or the cured print matrix. Overall, the release of the notified polymer and therefore exposure will be low. Therefore, the risk to workers from exposure to the notified polymer is considered to be low.

6.3.2. Public health

Overall, risk for the public from the use of the notified polymer is expected to be low, due to the likely low exposure and the non hazardous nature of the notified polymer.

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 in Australia.

RELEASE OF CHEMICAL FROM USE
Environmental release of the notified polymer is summarised in the following table.

Source of release	*% Volume*	*Released to / Fate*
Residual notified polymer in cartridges and from spills.	≤1%	Landfill
Notified polymer on recycled printed paper	~49.5%	Landfill via Sewer
Notified polymer on printed paper	~49.5%	Landfill

RELEASE OF CHEMICAL FROM DISPOSAL
Notified polymer disposed of to landfill is expected to associate with soil and organic material and should be relatively immobile within the landfill environment. Over time, the notified polymer is expected to degrade by biotic and abiotic means to form simple organic compounds.

Notified polymer on printed paper sent for recycling, which is not removed during recycling is expected to be released via the trade sewer where the majority will be absorbed to sludge due to being entrapped within the toner matrix This is expected to be disposed of to landfill. Any remaining polymer that enters the aquatic environment is expected to eventually associate with soil and sediments, and over time degrade via biotic and abiotic processes to form simple organic compounds.

7.1.2 Environmental fate

No environmental fate data were submitted

7.1.3 Predicted Environmental Concentration (PEC)

Assuming 100% of the imported product is disposed of on paper, with 50% of paper (Nolan ITU) being recycled at recycling plants around Australia, and a worst case scenario where none of the chemical adsorbs to sludge, then Predicted Environmental Concentrations (PECs) are calculated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	3000	kg/year
Proportion expected to be released to sewer	50	%
Annual quantity of chemical released to sewer	1500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	5.77	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.4	µg/L
PEC - Ocean:	0.14	µg/L

7.2. Environmental effects assessment

No ecotoxicological data were submitted. Polymers without significant ionic charge are not likely to be hazardous to the aquatic environment. The notified polymer is not expected to cross biological membranes, due to its low solubility and high molecular weight and as such should not bioaccumulate.

7.2.1 Predicted No-Effect Concentration

As ecotoxicological data were not submitted, it is not possible to calculate a Predicted No-Effect Concentration (PNEC).

7.3. Environmental risk assessment

The notified polymer is not expected to enter the aquatic environment during normal use except via paper recycling. Most of the polymer is likely to be adsorbed on to sludge during wastewater treatment. Any polymer residues entering the aquatic environment are expected to associate with the sediments therefore, not remain in the water compartment and be available for assimilation by aquatic organisms.

As no ecotoxicity data are available, a PNEC and resultant Risk Quotient (Q) are unable to be calculated. However, given the low volume and diffuse release pattern, there should be an adequate safety margin and the overall environmental risk is expected to be acceptable.

8. CONCLUSIONS – SUMMARY OF RISK ASSESSMENT FOR THE ENVIRONMENT AND HUMAN HEALTH

8.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances.*

8.2. Human health risk assessment

8.2.1. Occupational health and safety

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

8.2.2. Public health

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

8.3. Environmental risk assessment

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

9. MATERIAL SAFETY DATA SHEET

The MSDS of the notified chemical provided by the notifier was reviewed by NICNAS and is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant. The MSDS was found to be in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). The MSDS for the products containing the notified polymer that will be imported in Australia was not submitted at the time of assessment. It will be submitted to NICNAS before the comencemet of import.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as used in the product inks:
  - Printers should be located in well-ventilated areas;
  - Avoid spillage of toner and generating of dust particles during maintenance

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as used in the product inks:
  - Protective gloves

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

- Atmospheric monitoring should be conducted by employers to measure workplace concentrations of nuisance dust during use of the products containing the notified polymer. The NOHSC exposure standard for atmospheric dust is 10 mg/m3.

- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- Do not allow material or contaminated packaging to enter drains, sewers or water courses

Disposal

- The notified polymer should be disposed of in landfill.

Storage

- Store in a cool dry place and away from direct sunlight.

Emergency procedures

- Spills/release of the notified polymer should be handled by collecting the cartridge intact and landfilled.
- Contain the spill and collect using a vacuum cleaner.

- Place waste in suitable sealed containers and follow state or local regulation for the disposal of the waste.

11. REGULATORY OBLIGATIONS

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 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 chemical has changed from component in printing inks, or is likely to change 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.

APPENDIX A: PHYSICO-CHEMICAL PROPERTIES

Water Solubility 1.5 mg/L at 20ºC

METHOD Samples of 400 and 40 mg of the notified polymer were added to 200 ml of water. The samples were shaken at 35 to 40 ºC for 1 hour and then allowed to stand for 24 hours. The sample was filtered and the recovered solid was dried. The water solubility was measured by the change of mass of the original sample as well as by measurement the change in the total organic carbon content of the water phase. The water solubility was determined to be 19 mg/L by mass balance and 1.5 mg/L by TOC.

Remarks Analytical Method

TEST FACILITY Toray Research Center Inc., Japan

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

Remarks There was no indication of hydrolysis or degradation of the polymer at pH 1.2, 4.0, 7.0 or 9.0, when tested by change of dissolved organic carbon, infrared spectra or GPC. The notified polymer is stable at different pH conditions.

TEST FACILITY Toray Research Center Inc., Japan

Partition Coefficient (n-octanol/water) Not determined

Remarks The notified polymer has low water solubility and would be expected to partition to the organic phase.

Adsorption/Desorption – screening test Not determined

Remarks The notified polymer has low water solubility and would be expected to adsorb to organic matter in soil.

TEST FACILITY

Adsorption/Desorption – main test Not determined

Dissociation Constant Not determined

Remarks The notified polymer has low water solubility and the determination of the dissociation constant is not required. The notified polymer contains aromatic hydroxyl groups which are expected to have pKa values between 10-12.

TEST FACILITY

Particle Size MMAD = 32.91 μm

METHOD In-house method - Coulter Multisizer.

Range (μm)	*Mass (%)*
<10.2	5.9
10.2-20	22.3
20.0- 31.2	19.8
31.2-43.5	15.6
43.5-54.3	9.6
54.3 – 67.8	7.6
67.8 – 84.5	6.7
84.5 – 105	4.9
>105	10.1

Remarks	The full test method was not provided. Mean diameter = 32.91 μm; respirable (<10 μm) = 5.9%; inhalable (<100 μm) = 92.4%.
TEST FACILITY	Toray Research Center Inc., Japan (not dated)

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