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

PUBLIC REPORT

KNW

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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 Energy.

This Public Report is 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**

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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/1985	Cintox Australia Pty Ltd	KNW	ND*	≤ 1 tonne per annum	Component of printer toners

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As limited toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified chemical as introduced in printer cartridges:
 - Operate in well-ventilated areas;
 - Avoid spillage of toner;
 - Avoid generation of dust particles from cartridges.

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

- Service personnel should wear disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified chemical and during routine maintenance and repairs.
- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of 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

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, physical 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 importation volume exceeds one tonne per annum notified chemical;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of printer toners, or is likely to change significantly;
 - the amount of chemical being introduced has increased, 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.

Safety Data Sheet

The SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Cintox Australia Pty Ltd (ABN: 63 122 874 613)
Suite 1, L2, 38-40 George Street
PARRAMATTA NSW 2150

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada, China, European Union, Japan, South Korea and United States

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

KNW

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 96%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: white powder

Property	Value	Data Source/Justification
Melting Point	~ 78 °C	SDS
Boiling Point	Not determined	Expected to be high based on the molecular weight
Density	Not determined	Imported and used as a component in printer toners
Vapour Pressure	Not determined	Expected to be low based on the chemical structure
Water Solubility	Not determined	Expected to be low based on the high molecular weight and predominantly hydrophobic structure
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities that could undergo hydrolysis at extreme pH conditions. However, significant

Partition Coefficient (n-octanol/water)	Not determined	hydrolysis is not expected under environmental conditions (pH 4-9) due to its expected low water solubility. Expected to be high based on predominantly hydrophobic structure
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on high molecular weight and expected low water solubility
Dissociation Constant	Not determined	Contains no dissociable functional groups
Particle Size*	3-20 µm (mean 6 µm) Inhalable fraction (< 100 µm): 100% Respirable fraction (< 10 µm): > 90%	Measured
Flash Point	310 °C (closed cup)	SDS
Flammability	Not determined	Not expected to be highly flammable based on the structure
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidising properties

* Data for the imported printer toner containing ≤ 15% notifier chemical

DISCUSSION OF PROPERTIES

For full details of the particle size distribution test, refer to Appendix A.

Reactivity

The notified chemical is expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of 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 not be manufactured in Australia. The notified chemical will be imported into Australia as a component of printer toners in sealed, purposely designed cartridges.

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 and Sydney

IDENTITY OF RECIPIENTS

Cintox Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified chemical will be imported as a component of printer toners in sealed, purposely designed cartridges and transported within Australia in the original containers by road.

USE

The notified chemical will be used as a component of printer toners (at ≤ 15% concentration) in sealed cartridges which will be handled by service technicians, office workers and home users.

OPERATION DESCRIPTION

No reformulation and repackaging of products containing the notified chemical are expected in Australia. Toner cartridges containing the notified chemical will be imported and sold to consumers for use in offices and at homes where they will be loaded into devices such as photocopiers and printers for printing purposes. To change the cartridge in a photocopier or printer, the seal tape will be removed and the cartridge will be placed into the device. The cartridge is designed not to release the toner until the seal tape is removed.

During the copying or printing operation, the toner will be transferred on to the substrate (primarily paper) and cured by heat.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage workers	1	12-24
Office workers	8	200
Maintenance workers	1	200
Retail workers	8	200

EXPOSURE DETAILS

The notified chemical will not be manufactured or reformulated in Australia and therefore no exposure is expected from this type of operations.

Transport, storage and retail workers

Exposure to the notified chemical during transport, storage and retail is expected only in the unlikely event of an accident where a container is damaged.

Service technicians

Service technicians will handle the sealed toner cartridges during printer/photocopier maintenance or repairs. Any empty or defective cartridges will be replaced with new ones. The technicians may come into contact with the notified chemical at a concentration $\leq 15\%$. The principal route of exposure is dermal. Inhalation exposure is not expected due to the sealed nature of the cartridges unless the seal tapes are removed or the cartridges are broken and toner dusts are formed. Exposure to toners containing the notified chemical should be minimised by the use of safe replacement procedures recommended by the manufacturer, by wearing gloves and ensuring adequate ventilation.

Office users

Printer/photocopier users in offices may be intermittently handling toner cartridges containing the notified chemical; however, the exposure to the notified chemical is expected to be less frequent than that experienced by service technicians. Exposure may be minimised by the use of safe replacement procedures recommended by the manufacturer.

6.1.2. Public Exposure

Public consumers may be intermittently handling toner cartridges containing the notified chemical when replacing the spent cartridges, and during maintenance and cleaning of home printers/photocopiers. Exposure of the public to the notified chemical through the use of photocopier/printer toner is expected to be similar to or less than that experienced by office workers. Exposure during maintenance and cleaning of home printers/photocopiers is expected to be less frequent than that experienced by service technicians. Exposure may be minimised by the use of safe replacement procedures recommended by the manufacturer.

After application to the substrate and once cured, the toner containing the notified chemical is expected to be bound to the substrate and not bioavailable.

6.2. Human Health Effects Assessment

No toxicology study reports were submitted for the notified chemical. The SDS included some toxicological information for the notified chemical and an imported toner product containing the notified chemical. The toxicological information is summarised in the following table.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>	<i>Data Source</i>
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; low toxicity	SDS
Rat, acute inhalation toxicity	LC50 > 5.66 mg/L/4 hour; low toxicity*	SDS
Rabbit, skin irritation	non-irritating*	SDS
Eye irritation (<i>in vitro</i>)	not classified*	SDS
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation*	SDS
Mutagenicity – bacterial reverse mutation	non mutagenic*	SDS

* Data for the imported printer toner containing $\leq 15\%$ notifier chemical

Based on the high molecular weight ($M_n > 1,000$ Da) of the notified chemical, absorption across biological membranes is expected to be limited.

The notified chemical does not contain any structural alerts of human health concern and is therefore expected to be of low toxicity. This is supported by the above toxicological information for the notified chemical and the imported toner product containing the notified chemical.

Health hazard classification

As limited toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the available information, the notified chemical is expected to be of low hazard. The notified chemical will be imported as a component of finished toners at $\leq 15\%$ concentration for photocopiers and printers. Occupational exposure to the notified chemical is expected to be minimised by the enclosed nature of the toner cartridges.

Compared to office workers, service technicians are anticipated to have greater level of exposure; however, the exposure is expected to be mitigated through placing photocopiers/printers in areas with adequate ventilation and the use of gloves.

Therefore, when used in the proposed manner, the risk to workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

Exposure of the public to the notified chemical is expected to be similar to or less than that experienced by office workers through the use of photocopier/printer toner. Exposure is expected to be minimised by the use of the safe replacement procedures recommended by the manufacturer.

Once deposited onto the substrates (primarily paper), the notified chemical is expected to remain bound to the substrate and not to be bioavailable.

Therefore, when used in the proposed manner, the risk to public health from use of the notified chemical 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 chemical will be imported into Australia as a component of laser printer toner in sealed ready-to-use toner cartridges. Release of the toner to the environment is not expected, as manufacturing and reformulation of the toner containing the notified chemical will not take place in Australia. Environmental release of the notified chemical during importation, transport and storage is likely to be limited to accidental spills and leaks.

RELEASE OF CHEMICAL FROM USE

During use, the majority of the notified chemical will be cured within an inert matrix and bound to substrates (primarily paper), and will not be released from printed substrates. Environmental release of the notified chemical is possible during paper recycling and from the disposal of used printer toner cartridges.

RELEASE OF CHEMICAL FROM DISPOSAL

Following use, spent toner cartridges containing residues of the notified chemical will be collected for recycling by the distributor, or be disposed of to landfill in accordance with local government regulations. Toner residues containing the notified chemical separated from the spent cartridges will be disposed of in accordance with local government regulations, most likely to landfill.

Based on its use in printer toner, the majority of the notified chemical is expected to share the fate of the printed substrates to which it is bound. It is assumed that 50% of the printed paper will be disposed of to landfill, and the remainder will undergo paper recycling processes. During paper recycling processes, waste paper is repulped using a variety of chemical treatments which, amongst other things, will enhance ink detachment from the fibres. Waste water containing the notified chemical will be released to sewer.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified chemical. The notified chemical is not expected to be readily biodegradable based on the findings for an analogue that was previously assessed to be not readily biodegradable by NICNAS.

Following its use in ink products, the majority of the notified chemical is expected to enter the environment from disposal of used paper to which the printer ink containing the notified chemical is bound. Approximately 50% of the notified chemical is expected to be disposed of to landfill as part of printed waste paper. When bound on the used paper, the notified chemical is not expected to be mobile or bioavailable in this form. Notified chemical in free form is not expected to be mobile or bioavailable either, based on its high molecular weight and expected low water solubility.

The remaining 50% of the notified chemical has the potential to be released to sewer after the de-inking of printed paper during paper recycling processes. Due to its sorptive nature and expected low water solubility, very little of the notified chemical is expected to partition to the supernatant water when being released to the sewer.

Bioaccumulation of the notified chemical in aquatic life is not expected as it is not expected to cross biological membranes due to its high molecular weight. In landfill, water or soil, the notified chemical is expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 50% of the paper products containing the notified chemical undergoing recycling, and the notified chemical to be released into sewers with no removal during recycling or STP processes. As the notified chemical bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment

Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year

Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200.0	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:	0.43	µg/L
PEC - Ocean:	0.04	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m³). Using these assumptions, irrigation with a concentration of 0.425 µg/L may potentially result in a soil concentration of approximately 2.835 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 14.17 µg/kg and 28.35 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted for the notified chemical. High molecular weight chemicals without significant ionic functionality are not expected to be toxic to the aquatic environment, which is supported by the measured ecotoxicity data for an analogue that was previously assessed to be not harmful to aquatic life by NICNAS. The analogue and the notified chemical are expected to have similar ecotoxicological profile based on their structural similarity and same functional groups. Furthermore, based on its high molecular weight, the notified chemical is not expected to bioaccumulate and be present in water at concentrations that are hazardous to aquatic organisms.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated since no ecotoxicity data for the notified chemical was submitted.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) is not calculated as the PNEC has not been calculated. The notified chemical does not contain significant ionic functionality and is considered to be of low hazard to aquatic organisms although small amounts of the notified chemical may be released to aquatic compartment based on its use. The majority of notified chemical disposed of to the sewer is expected to be removed by partitioning to sludge and sediment during sewage treatment plant processes. As a result, it is not likely to be present in ecotoxicologically significant concentrations in the aquatic environment.

In the aquatic environment, the notified chemical is not expected to bioaccumulate based on its high molecular weight. Therefore, based on its assumed low hazard and assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment at the maximum import volume.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Particle Size** 3-20 µm (mean 6 µm)

Instrument Multisizer 3

<i>Particle size(µm)</i>	<i>Population of particles (cumulative %)</i>	<i>Volume (cumulative %)</i>
3	4.10916	0.205211
4	6.84958	0.650584
5	23.9398	6.48204
5.04	25.0495	6.96661
6	49.6629	21.2706
8	85.5128	62.5548
10	98.229	92.046
12.7	99.9275	99.3587
14	99.9845	99.807
15	99.9909	99.869
16	99.9952	99.9271
20	100	100

Remarks Test substance was a printer toner product containing the notified chemical at $\leq 15\%$ concentration.

Test Facility Unspecified (data provided by the notifier)

BIBLIOGRAPHY

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 >.