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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Bontron X-11

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Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Bontron X-11

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Lanier Australia Limited
854 Lorimar St Port Melbourne Vic 3207

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 identity
CAS No.
Molecular weights
Molecular and structural formulae
IR spectrum
Import volumes

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)
CEC 574

NOTIFICATION IN OTHER COUNTRIES
USA and Korea

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Bontron X-11

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD IR and UV-Vis

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported in ready to use cartridges at <10% notified chemical.

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

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

USE
The notified chemical is used as a component of toner product (<10%) for colour photocopiers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated

IDENTITY OF RECIPIENTS
Lanier Warehouse (Sydney)

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in ready-to-use toner cartridges containing 220g toner or <10% notified chemical.

5.2. Operation Description

No manufacturing or reformulation occurs in Australia.

Trained customer service engineers will maintain the photocopiers. Replacement of photocopier toner cartridges involves removal of the old toner cartridge from the copier and directly loading the new cartridge.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport & storage	4-6	2-3 hours/day	10-15 days/year
Customer service engineers	100	5-20 min/day	200 days/year

Exposure Details
The toner containing the notified chemical will be contained in sealed cartridges. No reformulation or repackaging will take place in Australia. Hence, no exposure to the toner, or the notified chemical is expected during transportation and storage.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer is not manufactured or reformulated in Australia.

RELEASE OF CHEMICAL FROM USE
Virtually all of the notified chemical will eventually be released to the environment. Approximately 80% of the notified chemical will be bound to paper, which will be buried in landfills, incinerated or recycled. Recycling of printed paper could result in release of a proportion of the notified chemical to the aquatic compartment in the resultant effluent or sludge. However, the environmental concentration is expected to be low due to dispersed disposal. Where recycling does not occur, the notified chemical will be disposed of to landfill where it is expected to remain bound to the paper.

The remaining 20% approximate will also be land filled contained in spent cartridges.

5.5. Disposal

The majority of the notified chemical will either be disposed of to landfill or incinerated. Small amounts may also be released to sewer as a result of paper recycling processes.

5.6. Public exposure

It is expected that during transport, storage, and use by customer service engineers, exposure of the general public will be minimal, except in the event of an accidental spill of toner.

Public exposure to the notified chemical would occur when handling photocopied paper. Consequently, any exposure is likely to be dermal.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Grey powder

Melting point/ Boiling Point Decomposed at >191°C (in air)

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks Decomposed at >191°C in air and at 181°C in nitrogen, by differential scanning calorimetry using computer-generated estimates, the melting point is 313±30°C and the boiling point>360°C
TEST FACILITY Safepharm Laboratories (2000a)

Density 1200 kg/m^3 (sourced from MSDS)

Vapour Pressure <5.1 x 10^{-8} kPa at 20°C

METHOD EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks Vapour pressure balance system.
The maximum value for vapour pressure was estimated using a regression slope based on a chosen data point from Run 7. The reading at 227 °C was chosen because this is the data point which gives the highest estimated vapour pressure at any given temperature. The result indicates that the notified chemical is very slightly volatile (Mensink, 1995).
TEST FACILITY Safepharm Laboratories (1999a)

Water Solubility <7.87x10^{-5} g/L at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility – flask method.
Remarks Analytical Methods:
1) Atomic Absorption Spectrophotometry – analysis to determine the concentration of metallic ion in solution thus indicating the water solubility of the notified chemical.
2) HPLC - analysis to determine the concentration of organic acid in solution thus indicating the water solubility of the impurity.

Three test flasks were set-up, each with approximately 0.1 g of test substance (0.1003, 0.1050 or 0.1002 g) and 1000 mL of glass double distilled water. The flasks were shaken at 30°C for either 24, 48 or 72 hours, allowed to stand for 24 hours at 20°C and then the contents were filtered. The filtrate was then analysed by AAS and HPLC. The pH of the solution was measured at the end of the study.

Since negligible metallic ion was detected in the three samples, the concentration of the test substance is based on the limit of detection during the analysis. The water solubility was determined to be <7.87x10^{-5} g/L based on the concentration of metallic ion in the solution.

The test chemical water solubility was determined to be 8.12x10^{-3} g/L based on the concentration of the impurity in the solution. The impurity is present in the test substance at 20%, with the remaining 80% consisting of the notified chemical. The higher water solubility based on the concentration of the impurity is probably the result of dissolution of the impurity not of the notified chemical or its breakdown

products.

The results indicate that the notified chemical is very slightly water soluble (Mensink, 1995).

TEST FACILITY Safepharm Laboratories Limited (2000a)

Hydrolysis as a Function of pH Not determined

Remarks The test was not conducted due to the insolubility of the notified chemical in water. The chemical does contain some functional groups that may undergo hydrolysis in the environment under pH conditions 4-9.

Partition Coefficient (n-octanol/water) log Pow at 20ºC = >3.9, estimation based on solvent solubility

log Pow at 20ºC = 6.1, estimation based on chemical structure (KOWWIN)

METHOD Alternate estimation methods

Remarks The notified chemical was found to be unstable under the shake flask method (as specified under EC Directive 92/69/EEC A.8 Partition Coefficient) with a solid precipitating out in the n-octanol phase. Since it contains a metal complex, the HPLC method was not applicable. Therefore two estimation methods were use.

In one its solubility in n-octanol and in water were determined, from which the log P_{ow} was estimated. The computer model KOWWIN, which uses atom/fragmentation calculation based on the structure of the chemical, was the other method used.

The solvent solubility method estimated log P_{ow} to be > 3.9, while KOWWIN estimated it to be 6.1.

TEST FACILITY Safepharm Laboratories Limited (2000b)

Adsorption/Desorption Not determined.

Remarks The notified chemical has a high log P_{ow} , therefore will adsorb to organic matter in soils and sediments. Due to its charge ion exchange with soil components may also occur.

Dissociation Constant Not determined

Remarks The notified chemical is a metal complex, so it may dissociate in water.

Particle Size Mean particle size of toner particles is 5-8 μm.

Flash Point Not applicable

Flammability Limits Not classified as highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids).

Remarks Bontron X-11 did not propagate combustion over the 200 nm of the preliminary screening test in under 4 minutes.

TEST FACILITY Safepharm Laboratories Ltd (1999b)

Autoignition Temperature Not expected to autoignite

Remarks Pyrophoric properties of the notified chemical were not determined due to expected negative results based on the chemical structure and known physical and chemical properties.

Explosive Properties Not expected to be explosive

Remarks Explosive properties of the notified chemical were not determined due to expected negative results based on the chemical structure and known physical and chemical properties.

STATEMENT Safepharm Laboratories Ltd

Reactivity Incompatible with oxidising agents, strong acids and strong bases.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD_{50} between 200 and 2000 mg/kg bw Harmful
Rabbit, skin irritation	Non-irritating
Rabbit, eye irritation	Slightly irritating
Guinea pig, skin sensitisation - adjuvant test	No evidence of sensitisation.
Genotoxicity - bacterial reverse mutation	Non mutagenic

7.1. Acute toxicity – oral

TEST SUBSTANCE Bontron X-11

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain Rat/Sprague-Dawley CD
Vehicle Arachis oil BP
Remarks – Method GLP & QA.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 females	2 000	3/3
2	3 females	200	0/3
3	3 males	200	0/3

LD50 Between 200 and 2 000 mg/kg bw
Signs of Toxicity After treatment with 2 000 mg/kg, the females showed signs of ataxia, hunched posture, lethargy, decreased respiratory rate and laboured respiration with isolated incidences of pallor of the extremities, prostration, noisy respiration and splayed gait.

After treatment with 200 mg/kg, the females displayed laboured respiration and/or hunched posture. One female had red/brown staining around the snout area. All females recovered within 1-2 days after treatment. No clinical signs of toxicity were observed in males at 200 mg/kg.
Effects in Organs At dose level of 2 000 mg/kg, animals had abnormally red lungs, dark livers, dark kidneys, black-coloured substance in stomach, pale gastric mucosa and sloughing of the non-glandular epithelium of the stomach.

No abnormalities were observed in animals treated at 200 mg/kg.
Remarks – Results Harmful (Xn) with R22 (Harmful if swallowed) should be assigned.

CONCLUSION The notified chemical is harmful via the oral route.

TEST FACILITY Safepharm Laboratories Limited (2000b)

7.2. Irritation – skin

TEST SUBSTANCE	Bontron X-11
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Vehicle	Water.
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.
RESULTS	Draize scores for erythema/eschar and oedema were zero for all animals during 72 hour observation period.
Remarks - Results	None.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	Safepharm Laboratories Limited (2000c)

7.3. Irritation – eye

TEST SUBSTANCE	Bontron X-11
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	3
Observation Period	72 hours
Remarks - Method	GLP & QA.

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	1	1 hour	0
Conjunctiva: chemosis	0	0	0	1	1 hour	0
Conjunctiva: discharge	0	0	0	1	1 hour	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	Black/grey coloured staining of the fur around the treated eyes were noted in all 3 animals up to 72 hours.
CONCLUSION	The notified chemical is slightly irritating to the eye.
TEST FACILITY	Safepharm Laboratories Limited (2000d)

7.4. Skin sensitisation

TEST SUBSTANCE	Bontron X-11
METHOD	OECD TG 406 Skin Sensitisation – maximisation test.

	EC Directive 96/54/EC B.6 Skin Sensitisation - maximisation test.
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: <0.5% topical: 5%
MAIN STUDY	
Number of Animals induction phase	Test Group: 10 Control Group: 5 Induction Concentration: intradermal injection 0.5% topical application 50%
Signs of Irritation	After intradermal injections, discrete or patchy erythema was observed at the induction sites in test animals. After topical induction, precluding evaluation of erythema and very slight oedema were observed in test animals. Black/brown coloured staining was also observed at the topical induction sites. The staining did not affect the evaluation of skin responses.
CHALLENGE PHASE	
1st challenge	topical application: 25% topical application: 10%
Remarks - Method	GLP & QA.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	25%	0/10	0/10		
	10%	0/10	0/10		
Control Group	25%	0/5	0/5		
	10%	0/5	0/5		

Remarks - Results	Three test animals had black/brown coloured staining at the topical induction sites. The staining did not affect the evaluation of skin responses. One challenge site was physically damaged by the removal of adhered patches after challenge.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Safepharm Laboratories Limited (2000e)

7.5. Genotoxicity - bacteria

TEST SUBSTANCE	Bontron X-11
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2 uvrA.
Metabolic Activation System	S9-mix
Concentration Range in Main Test	a) With metabolic activation: 0-5 000 µg/plate. b) Without metabolic activation: 0-5 000 µg/plate.
Vehicle	Acetone.
Remarks - Method	GLP & QA.

RESULTS

Metabolic	*Test Substance Concentration (µg/plate) Resulting in:*

Activation	*Cytotoxicity in PreliminaryTest*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	≥5 000	≥1 500		
Test 1		5 000	5 000	None.
Test 2		5 000	5 000	None.
Present	≥5 000			
Test 1		5 000	5 000	None.
Test 2		5 000	5 000	None.

Remarks - Results: A black precipitate was observed at 5 000 µg/plate, this did not prevent the scoring of revertant colonies.

CONCLUSION: The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Safepharm Laboratories Limited (2000f)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Bontron X-11

METHOD

Inoculum: Mixed population of activated sewage sludge micro-organisms from the aeration stage of the Severn Trent Water STP at Belper, Derbyshire.

Exposure Period: 28 days

Auxiliary Solvent: None

Analytical Monitoring

Remarks - Method: The biodegradation of the notified chemical was determined by the measurement of oxygen uptake after the medium was inoculated with a mixed population of aquatic microorganisms and stored in the dark at 22°C for 28 days. The following treatments were undertaken:

- control with inoculated culture medium – in duplicate;
- reference substance in inoculated culture at concentration of 10 mg C/L – in duplicate;
- test substance in inoculated culture at concentration of 10 mg C/L – in duplicate; and,
- toxicity control - test substance with reference substance in inoculated culture at concentration of 20 mg C/L.

Sodium benzoate was used as a reference substance.

RESULTS

Bontron X-11		*Sodium benzoate*		*Bontron X-11 and Sodium benzoate*	
Day	*% degradation*	*Day*	*% degradation*	*Day*	*% degradation*
0	0	0	0	0	0
1	3	1	21	1	9
2	7	2	46	2	10
3	6	3	62	3	30
6	3	6	68	6	28
8	5	8	66	8	31
10	9	10	71	10	38
14	7	14	71	14	40
16	11	16	79	16	39

20	11	20	86	20	43
22	11	22	88	22	43
24	11	24	86	24	45
27	12	27	90	27	48
28	13	28	90	28	47
29	18	29	92	29	48

Remarks – Results

The reference substance reached a degradation greater than 60% by day 14, thus validating the study.

The toxicity control (Bontron X-11 and Sodium benzoate) reached a degradation greater than 25% by day 14, therefore indicating that the test substance was non-inhibitory to the study.

CONCLUSION

The notified chemical did not reach 60% or greater degradation by day 28, therefore cannot be considered readily biodegradable.

TEST FACILITY

Safepharm Laboratories Limited (1999c)

8.1.2. Bioaccumulation

No studies or data are available on the bioaccumulation of the notified chemical. With a log P_{ow} estimated to be greater 3.9, the notified chemical has the potential to bioaccumulate (Connell, 1990)

8.2. Ecotoxicological investigations

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE

Bontron X-11

METHOD

OECD TG 202 Daphnia sp. Acute Immobilisation.

Species: *Daphnia magna*
Exposure Period: 48 hours
Auxiliary Solvent: Acetone
Water Hardness: Not stated
Analytical Monitoring: HPLC, AAS

Remarks – Method

Due to the test substance's low water solubility and the presence of the impurity, the method of aqueous media preparation was modified. The test media was prepared by column elution rather than as a Water Accommodated Fraction. The media was prepared by dissolving 500 mg of the test substance in acetone with the aid of ultrasonication for 1 minute. Acetone was then added to give a solvent stock solution of 500 mg/50 mL. Aliquots of the stock solution were added to the column with approximately 5 cm of glass beads. The acetone was then evaporated off using compressed air and reconstituted water at a rate of 60 mL/minute for 120 hours. After 120 hours it was believed that a saturated solution would have been achieved.

Ten (10) daphnia were added to each test vessel, which already contained 200 mL of solution. All vessels were covered and maintained at 21°C with a photoperiod of 16 hours light and 8 dark. The daphnia were not fed during the study and the vessels were not aerated. There was no renewal of media throughout the study. The control and the solvent control were done in duplicate, while the test was done in quadruplicate. The water temperature was recorded daily, while dissolved oxygen and pH were measured at the start and finish of the study.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
Control		20 (2 replicates + 10 daphnia each)	0	0
Solvent control		20 (2 replicates + 10 daphnia each)	0	0
0.1		40 (4 replicates + 10 daphnia each)	0	0

LC50	>0.1 mg/L at 48 hours
NOEC (or LOEC)	0.1 mg/L at 48 hours
Remarks – Results	No abnormal behaviour or immobilisation was observed throughout the study. The test substance consisted of 80% Bontron and 20% organic acid impurity. Since it was a mixture, the toxicity cannot be attributed to a specific component but rather to the mixture itself.
CONCLUSION	This study is not very definitive. It appears that the test substance is toxic up to its water solubility limits.
TEST FACILITY	Safepharm Laboratories Limited (2000g)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Release of the toner containing the notified chemical to the environment is not expected under normal use, as the cartridge is designed to prevent leakage. However, if leakage does occur, the ink will be contained and presumably disposed of to landfill. Environmental exposure will result from the disposal of printed paper and discarded cartridges as well as the possibility of accidental leakage of the cartridges during use. Ink residues contained in the empty cartridges are expected to be approximately 23% of the import volume and to remain within these containers, although release could occur from deterioration of the cartridge. The total import volume of the notified chemical will ultimately be disposed of to landfill or be incinerated or to paper recycling.

Waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. In landfill the paper and the notified chemical would undergo biotic and abiotic degradation. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon and iron.

Approximately 20% of the printed paper will go to recycling. During the recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. De-inking wastes include a sludge and liquid effluent. The effluent is expected to go to trade waste sewers. It is likely that the notified chemical would end up in the sludge. Trade sources estimate the washing process will recover 30-60% of the total amount of ink, therefore at least 30% of the notified chemical in the recycled paper will be disposed of with sludge to landfill.

Assuming a worst-case situation in which the entire import volume (1000 kg) is released to sewer and not removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 2.7 kg/day. Assuming a national population of 19,500,000 and that each person contributes an average 200 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 0.7 μg/L (0.7 ppb).

Due to its low water solubility (<$7.87x10^{-5}$ g/L) and its potentially high partition coefficient (log P_{ow} >3.9), the notified chemical does have the potential to bioaccumulate. (Connell 1990). However, this potential is limited by the notified chemical's low exposure to the aquatic compartment.

Abiotic or slow biotic processes are expected to be largely responsible for the degradation of the notified chemical as it is not readily biodegradable. As a consequence of its anionic nature, the notified chemical is likely to be immobilised through adsorption onto soil particles and sediments.

9.1.2. Environment – effects assessment

The only ecotoxicity data provided was an acute daphnia toxicity study. The result of the study indicates that the LC_{50} is greater than 0.1 mg/L. At this level the notified chemical would be very toxic to aquatic organisms. Since only one concentration was tested (0.1 mg/L) the study is inconclusive. The chemical's toxicity could also be in excess of 100 mg/L, in which case it would not be considered toxic.

A predicted no effects concentration (PNEC) cannot be determined when there is only one piece of data. With such a low water solubility it is unlikely that under normal environmental conditions will the concentration in water exceed 0.1 mg/L. Solid material may be present which may aggravate aquatic organisms. However, it is very unlikely that the notified chemical will be directly released into the environment.

9.1.3. Environment – risk characterisation

Based on the import volume, method of packaging and low concentration in toner, release of the notified chemical to the environment is expected to be low and widespread since it will be used across Australia.

It is likely that the PEC/PNEC ratio for the aquatic environment will be much less than 1, indicating no immediate concern to the aquatic compartment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Occupational exposure to the notified chemical in Australia will primarily concern copier service personnel. Customer service engineers will be required to change the toner cartridge. The used cartridge is removed from the machine and replaced with the new cartridge without direct contact with the toner contained in the cartridge. Inhalation and dermal exposure to the toner powder may occur during toner replacement, particularly in the event of a container leak or spill. Other service operations such as cleaning the inside of the machine and servicing the machine may also involve contact with toner particles remaining in the interior of the machine or disturbance of toner dust leading to inhalation exposure. The customer service engineers will wear cotton gloves if the maintenance procedure involves direct contact with the toner.

Exposure may occur upon handling printed matter. However, very little toner is used per sheet of paper and it would not be separately available for exposure or dermal uptake as it is fused and fixed to the printed surface. These considerations indicate there would be no human exposure to the notified chemical during the handling of printed materials.

9.2.2. Public health – exposure assessment

The notified chemical will not be sold to the public. Toner cartridges will be changed by customer service engineers. Public exposure will occur by dermal contact with photocopied media, whose toner will contain <10 % of the notified chemical.

9.2.3. Human health - effects assessment

The acute oral toxicity study for the notified chemical was performed according to the acute oral toxic class method of OECD TG423. All rats died at the dose level of 2 000 mg/kg but survived at 200 mg/kg. Systemic and/or organ toxicity was observed in rats after treatment with the notified chemical. The notified chemical is classified as 'harmful' on the basis of its acute

toxicity.

The notified chemical was not a skin irritant in rabbits or a skin sensitiser in guinea pigs, but was a slight eye irritant in rabbits.

The notified chemical was not mutagenic either with or without metabolic activation in an Ames test.

The toner containing notified chemical at <10% is in powder form with mean particle size of <10 μm (respirable). The toner can be considered a nuisance dust and employers are responsible for maintaining atmospheric levels of toner dust below the NOHSC exposure standard of 10 mg/m^3 TWA[1] (NOHSC, 1995). Australia does not have a national exposure standard for respirable dust, however, the ACGIH TLV[2] is 3 mg/m^3 TWA (ACGIH, 2001).

9.2.4. Occupational health and safety – risk characterisation

The main exposure will be to service personnel who will be responsible for changing toner cartridges containing <10% notified chemical. The design of the toner cartridges is such that exposure to the notified chemical should be minimal, even when changing toner cartridges. Minor dermal or inhalation exposure may occur if a small quantity of toner is spilt while changing cartridges.

Office workers are not expected to come into contact with the notified chemical under normal circumstances. Infrequent dermal exposure of end users to the toner containing the notified chemical may occur during servicing or clearing paper jams, but the high molecular weight of the notified chemical indicates that dermal absorption would be minimal. There may be a low level of toner dust in the immediate vicinity of photocopiers when they are operating. Exposure to the notified chemical is not expected to occur once the toner is bound to paper.

Based on the low toxicological hazard presented by the notified chemical and the expected low exposures, the health risk posed to office workers and service personnel by the notified chemical is very low.

Waterside, warehouse and transport workers will be only exposed to the notified chemical in the event of an accident or damage to packaging. The occupational health risk to these workers is negligible, considering the small quantities in individual toner cartridges and the low hazard presented by the chemical.

9.2.5. Public health – risk characterisation

Given the notified chemicals low toxicity and manner of exposure, the risk from public exposure to the notified chemical is considered to be low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

Harmful (Xn) with R22 (Harmful if swallowed).

10.2. Environmental risk assessment

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

[1] Time Weighted Average
[2] Threshold Limit Value

pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the and products containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the products containing the chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified chemical:
  - Harmful (Xn) with R22 (Harmful if swallowed).

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥25%: Harmful (Xn) with R22 (Harmful if swallowed).

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical:
  - Work areas around photocopiers should be well ventilated.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
  - Workers using the product should implement good work practices to avoid spills and the generation of dust.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
  - Gloves should be worn if direct contact with toner is possible.

  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 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

- The following control measures should be implemented by the notifier, distributor and end-user to minimise environmental exposure of the notified chemical:
  - Contain spills and clean-up quickly. Place spilt material into a closable container and dispose of to landfill.

Disposal

- The notified chemical should be disposed of in landfill by recycling or incineration.

Emergency procedures

- Spills/release of the notified chemical should be handled by containment and mechanically cleaning up (eg sweeping or vaccuming).

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

Under Subsection 64(2) of the Act:

- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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