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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

HME-313

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ricoh Australia Pty Ltd (ABN: 30 000 593 171) of 8 Rodborough Rd, Frenchs Forest, NSW 2086

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
Spectral data
Purity and nature of impurities
Introduction volume
Detailed use

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
Japan, China, Korea, The Philippines

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
HME-313

METHODS OF DETECTION AND DETERMINATION

METHOD	Infrared Spectroscopy, UV/Vis Spectroscopy, ^{1}H NMR
Remarks	Comparison of IR traces to the standard provided will enable identification of the notified chemical. Identity also confirmed by UV/Vis Spectroscopy and ^{1}H NMR.

3. COMPOSITION

DEGREE OF PURITY **Non-Confidential**
97-100%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as a component of ink in sealed inkjet printer cartridges at a concentration of up to 20%.

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

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

USE
Component of printing ink.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
The product will be supplied to offices nationwide and office equipment retailers.

TRANSPORTATION AND PACKAGING
Individual cartridges (larger cartridge < 80g capacity, small cartridge < 60g capacity) will be packed in sturdy cardboard boxes and would normally be imported by ship in containers and transported by road. The inkjet printing system containing the notified chemical is not a dangerous good, hazardous substance, or scheduled poison, and therefore no special transport or packaging requirements are necessary.

5.2. Operation description

No reformulation or repackaging of the imported product containing the notified chemical occurs in Australia. Sealed ink cartridges containing the notified chemical will be handled by service technicians or office workers or the public, who will replace spent cartridges in the printers as necessary. Office workers and the public will also use the printers for varied printing work. The ink cartridges containing the notified chemical are designed for a single use, and will not be refilled.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Service technicians (estimate)	10	8 h/day	230 days/year
Office workers	1000	5 to 10 minutes/day	10 days/year

Exposure Details

Dermal or inhalation exposure of workers to the notified chemical could occur during replacement of cartridges in the printers, or during normal use of the printers. Both service technicians and office workers would experience the same types of exposure, but exposure duration is likely to be greater for the former.

Exposure while changing cartridges is expected to be limited to dermal exposure, occurring if the ink is inadvertently touched. However this would be avoided by users and would be evident if it occurred. Occasional dermal exposure during use of the printer could occur if the printed pages were touched inadvertently before the ink had dried, or if ink-stained parts of the printer were touched. Once the ink dries, the chemical would be trapped in the printed paper, and therefore dermal exposure to the notified chemical from contact with the dried ink is not expected.

Routine inhalation exposure to vapour or aerosol could occur during use of the printer. A proportion of the notified chemical is expected to evaporate from the printed page during the drying process. While some continuing evaporation of the notified chemical may occur after the main print drying process, based on the vapour pressure of the notified chemical, this is expected occur at a very slow rate and produce very low concentrations in air.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The product is imported into Australia in its end-use containers, and will not undergo any further reformulation. Therefore, no environmental release is expected apart from that from accidental spills during transport or handling accidents.

RELEASE OF CHEMICAL FROM USE

Under normal use conditions, environmental release of the notified chemical from the cartridge is not expected. In the case of spills, it is expected that the notified chemical will be contained by absorbent materials and disposed of to landfill.

Once the notified chemical is applied to paper, the majority of the notified chemical is expected to remain sorbed to the paper or trapped within the print. Some may evaporate during and after printing. The deposited ink volume on the paper is estimated by the notifier to be 0.06 g/page (total of 4 colour ink system).

Paper to which the notified chemical will be bound within the print will eventually be disposed of to landfill, be incinerated, or be recycled. In the case of the latter, the notified chemical may be released in effluent from the de-inking process. However, the notifier expects very little if any of the notified chemical to remain to this stage, as the notified chemical is moderately volatile, with respect of environmental release.

Residues left in empty cartridges (estimated to be less than 1% total import volume) are expected to be disposed of to landfill. Spent cartridges may also be recycled or reused along with all residual ink in the recycling process. Spent cartridges that are not recycled are expected to be disposed of to landfill.

5.5. Disposal

It is expected that the spent cartridges containing residual notified chemical will either be disposed of to landfill or be recycled. Notified chemical may also be disposed of indirectly from waste paper containing the notified chemical via recycling, to landfill or by incineration.

5.6. Public exposure

The scenarios by which the public may be exposed to the notified chemical would involve home use of printers, and are similar to those for office workers (see section 5.3 above). However, it is expected that the public will be using the printer less often than workers.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Clear, Colourless liquid

Freezing Point < -25ºC

METHOD	OECD TG 102 Melting Point/Melting Range. EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	No significant protocol deviations. The notified chemical did not solidify as the temperature was decreased from ambient temperature down to -25 ºC.
TEST FACILITY	Huntingdon Life Sciences (2005)

Boiling Point 203ºC at 101.3 kPa

METHOD	OECD TG 103 Boiling Point – modified Siwoloboff method EC Directive 92/69/EEC A.2 Boiling Temperature – modified Siwoloboff method
Remarks	The boiling point was determined as the point at which a rapid stream of bubbles is seen.
TEST FACILITY	Huntingdon Life Sciences (2005)

Density 974 - 982 kg/m^3

Remarks	Data taken from MSDS. No study report reviewed.

Vapour Pressure 0.000966 kPa at 20ºC (Taken from MSDS)
0.006479 kPa at 25ºC (Antoine Method – MPBPWin v 1.40)
0.005252 kPa at 25ºC (Modified Grain Method – MPBPWin v 1.40)
0.063328 kPa at 25ºC (McKay Method – MPBPWin v 1.40)

Remarks EPIWIN selected a vapour pressure of 0.005866 kPa at 25ºC being the mean of the Antoine and Modified Grain methods. According to the classification scheme of Mensink *et al*, 1995, the notified chemical is moderately volatile with respect to environmental release. For inhalation exposure considerations, the notified chemical is considered to be of low volatility (European Commission 2003)

Water Solubility >1000 g/L at 20ºC (Measured)
8.25 x 10^7 g/L (Estimated)

METHOD OECD TG 105 Water Solubility –Preliminary Test
EC Directive 92/69/EEC A.6 Water Solubility- Preliminary Test
Estimation method - WSKOW v1.41
Remarks No significant protocol deviations. Approximately 0.1g of the notified chemical was found to dissolve readily in 0.1 ml of purified water.
TEST FACILITY Huntingdon Life Sciences (2005)

Henry's Law Constant 1.69 x 10^{-10} atm-m^3/mole (log H –9.77) (Estimated)

METHOD Estimation method – HENRYWIN v3.10

Hydrolysis as a Function of pH Not determined.
Remarks There are no hydrolysable groups present.

Partition Coefficient (n-octanol/water) $LogP_{OW}$ = -0.56 at 20ºC (Measured)
log K_{OW} = 0.16 at 20ºC (Estimated)

METHOD EEC Method A8, OECD Method 107
Estimation method - KowWin Program v1.66
Remarks
TEST FACILITY Huntingdon Life Sciences (2005)

Adsorption/Desorption – screening test log K_{oc} = 1.1 ±1.0 at 25°C

METHOD Estimation using ACD Software (K_{OC} = 1 by PCKOC v 1.66)

Dissociation Constant Not applicable

Remarks Based on its structure the notified chemical is not expected to dissociate in water as it has no dissociable groups.

Particle Size Not applicable

Remarks The notified chemical is a liquid

Flash Point 103ºC at 103.5 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point – Closed Cup
Remarks Determined in duplicate according to BS6664 Part 5.
TEST FACILITY Huntingdon Life Sciences (2005)

Flammability Limits Upper: 24%

Lower: 0.8%

Remarks Data taken from MSDS. No study report reviewed.

Autoignition Temperature Not determined

Remarks The notified chemical is not expected to autoignite under normal conditions of use.

Explosive Properties Not predicted to be explosive

Remarks There are no chemical groups that would imply explosive properties, therefore the result has been predicted to be negative

Reactivity

Remarks The notified chemical is stable at room temperature for normal storage and handling. Avoid contact with strong oxidizers and organic peroxides. Hazardous decomposition products are carbon oxides. The notified chemical will not undergo hazardous polymerisation.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Mice, acute oral	low toxicity, LD50 >5000 mg/kg bw
Rabbit, skin irritation (acute)	non-irritating
Rabbit, skin irritation (repeat dose)	slightly irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – bacterial DNA damage test	negative

7.1. Acute toxicity – oral

TEST SUBSTANCE: HME-313

METHOD: Test was reported to be carried out in accordance of OECD and EPA guidelines and EEC regulations at the time.

Species/Strain: Mice/CD-1

Vehicle: Distilled water

Remarks - Method: No significant protocol deviations from OECD TG 401. The study was performed in accordance with GLP.

A dose ranging study was conducted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Dose Ranging Study			
I	2 per sex	100	0
II	2 per sex	500	0
III	2 per sex	1000	0
IV	2 per sex	3000	0
V	2 per sex	5000	0
Main Study			
I	5 per sex	2000	0
II	5 per sex	5000	0

LD50: >5000 mg/kg bw

Signs of Toxicity: No clinical signs were noted at any time after dose administration. Body weight gains were within acceptable range.

Effects in Organs: No abnormalities were noted at gross post mortem examination

Remarks - Results

CONCLUSION: The notified chemical is of low toxicity via the oral route.

TEST FACILITY: IRI (1987a)

7.2.1 Irritation – skin (Acute)

TEST SUBSTANCE: HME-313

METHOD: Acute dermal irritation test was carried out in accordance with USFDA Code of Federal Regulations Title 16, Section 1500.41, performed on MBD

Species/Strain: Rabbit/New Zealand White

Number of Animals	3 per sex
Vehicle	Test substance administered as supplied
Observation Period	72 hours
Type of Dressing	Occlusive
Remarks - Method	Deviation from OECD TG 404 Acute Dermal Irritation/Corrosion – Test substance applied to both abraded and unabraded test sites on each animal. – Exposure period 24 hours compared with 4 hours in current OECD test method. – Skin reactions were assessed at 24 hours and 72 hours only. The study was performed in accordance with GLP.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	0	N/A	0
Oedema	0	0	N/A	0

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

Remarks - Results

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY IRI (1987b)

7.2.2 Irritation – skin (Repeat Dose)

TEST SUBSTANCE HME-313

METHOD Not specified – The dermal irritation potential of the notified chemical, following repeat application, was investigated in New Zealand White Rabbits and compared with that of a control site without test material.

Species/Strain	Rabbit/New Zealand White
Number of Animals	Eight male animals
Vehicle	Test substance administered as supplied
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Duration of exposure (dermal): 24 hours/day Post-exposure observation period: None
Type of Dressing	Occlusive
Remarks - Method	After the exposure period (24 hours) the patches were removed and the skin assessed immediately prior to repeat patch application. After completion of the final skin assessment (day 29), the rabbits were sacrificed and the sites evaluated histopathologically. The study was performed in accordance with GLP.

RESULTS

Signs of Irritation	No skin irritation was noted except for very slight erythema (barely perceptible) in 2 animals at day 18. Very slight erythema and very slight oedema (barely perceptible) were noted in one animal at day 15 and another animal at day 27. No irritation was noted on the control site. When the sites were examined histopathologically, the only lesion seen was very mild inflammatory cell infiltration, which occurred in 4 animals at the test site (MBD) compared with 2 animals at the control site.
Mortality	Two rabbits died during the study. One rabbit was found dead on day 10.

This rabbit had a gastrointestinal disease but further diagnosis was not possible and death was considered unrelated to treatment. This rabbit was replaced with another rabbit. Another rabbit was found dead on day 22 and was not replaced. The cause of death for this animal could not be diagnosed.

Signs of Toxicity: All surviving animals showed reasonable weight gain over the study period and the group mean body weight gain is considered to be within the acceptable range.

Statistically significant (P>0.05) reductions in food consumption were noted for weeks 1 (25% reduction) and 3 (5% reduction), when compared with the pre-trial mean food consumption value.

No significant differences were noted in weekly water consumption over the study period.

Remarks - Results

CONCLUSION: The notified chemical is very slightly irritating to the skin under the conditions of this test.

TEST FACILITY: IRI (1987c)

7.3. Irritation – eye

TEST SUBSTANCE: HME-313

METHOD: This test was carried out in accordance with USFDA Code of Federal Regulations Title 16, Section 1500.42, performed on MBD.

Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 per sex
Observation Period: 7 days
Remarks - Method: No significant deviation from OECD TG 405 Acute Eye Irritation/Corrosion. The study was performed in accordance with GLP.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0	0	0	0
Conjunctiva: chemosis	0	0	0	0
Conjunctiva:discharge	0	0	0	0
Corneal opacity	0	0	0	0
Iridial inflammation	0	0	0	0

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

Remarks - Results

CONCLUSION: The notified chemical is non-irritating to the eye.

TEST FACILITY: IRI (1987d)

7.4. Skin sensitisation

TEST SUBSTANCE: HME-313

METHOD: Magnusson-Kligman Maximisation Test

Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: 5-10% (slight irritant response) topical: 50% (non-irritating), 100% (slight irritant reponse)
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 10% in distilled water topical: 100% (test substance administered as supplied)
Signs of Irritation	Moderate erythema was noted in all test group animals following intradermal and topical induction. Slight erythema was noted in all control animals. The test sites were pre-treated with 10% sodium lauryl sulphate 24-hours before topical induction.
CHALLENGE PHASE	
1st challenge	topical: 50% in distilled water
Remarks - Method	No significant protocol deviations from OECD TG 406 Skin Sensitisation. The study was performed in accordance with GLP. Dichloronitrobenzene (DNCB) was used as a positive control.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group			
	50%	0/20	0/20
Control Group			
	50%	0/10	0/10

Remarks - Results	No clinical signs, except skin reactions induced by treatment, were noted at any time during the study. The positive responses noted for DNCB confirmed the sensitivity of the test.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	IRI (1987e)

7.5. Genotoxicity bacteria – reverse mutation assay

TEST SUBSTANCE	HME-313
METHOD	The procedures used are based on the method of Ames et al (1975) Pre incubation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA (pKM101)
Metabolic Activation System	S9 fraction from Aroclor 1254 induced rat liver.
Concentration Range in Main Test	a) With metabolic activation: 33 – 10000 µg/plate b) Without metabolic activation: 33 -10000 µg/plate
Vehicle	Dimethylsulfoxide
Remarks - Method	No significant deviations from OECD TG 471 Bacterial Reverse Mutation Test. The study was performed in accordance with GLP. 2-Aminoanthracene is used as the sole indicator of the efficacy of the S9-mix. Positive controls for strains tested with activation were methyl methane sulfonte (TA100), N-ethyl-N-nitro-N-nitrosoguanidine (TA1535

and WP2uvrA (pKM101)), 2-nitrofluorene (TA98) and 9-aminoacridine (TA1537).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 10000			
Test 1		>10000	>10000	negative
Test 2		>10000	>10000	negative
Present	> 10000			
Test 1		>10000	>10000	negative
Test 2		>10000	>10000	negative

Remarks - Results: No toxicity or precipitation was observed. The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of activation. Positive controls confirmed the sensitivity of the test system.

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

TEST FACILITY: IRI (1987f)

7.5.2 Genotoxicity bacteria - DNA damage test

TEST SUBSTANCE: HME-313

METHOD: Bacterial DNA damage test.
The procedures used are based on the methods of Kada et al (1980).

Species/Strains: *Bacillus subtilis:* H17 org$^-$ try$^-$ wild-type parental strain (recombination-proficient), M45 org$^-$ try$^-$ recA^{45} rec^{45} (recombination-deficient)

Metabolic Activation System: S9 fraction from Aroclor 1254 induced rat liver.

Concentration Range in Main Test: a) With metabolic activation: 6250 – 100000 µg/plate
b) Without metabolic activation: 6250 – 100000 µg/plate

Vehicle: Dimethylsulfoxide

Remarks - Method: An initial streak plate test was carried out, in the absence of S9 mix only to select suitable dose levels. No toxicity was noted at any of the concentrations tested (2.5, 25, 250, 2500 and 25000 µg/plate)

A liquid suspension assay was conducted as the main test. The test was carried out both in the presence and absence of activation. As the initial dose of the negative control (chloramphenicol) did not induce the expected toxicity, the test in the absence of activation was repeated. Triplicate plates were prepared for each of 5 dose levels and vehicle, negative and positive (ethyl methanesulphonate) controls.

The study was performed in accordance with GLP.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	>25000			
Test 1		100000	not reported	negative
Present	-			

Test 1	>100000	not reported	negative

Remarks - Results	The test detects agents that interact with cellular DNA to produce growth inhibition or killing. The response is expressed in the preferential inhibition of growth or the preferential killing of the DNA repair deficient strain (M45). In the presence of activation no inhibition of growth was observed in either strain at any of the doses tested. In the absence of activation, results were reported for the repeat study only. Inhibition of growth was observed at the highest concentration, but the survival percentage of the repair deficient strain (M45) (33%) was greater than the survival percentage of the repair proficient strain (H17) (12.5%) The positive control induced greater toxicity in Strain M45 than in Strain H17, particularly in the absence of S9 mix. The survival indices (survival % M45/survival % H17) for EMS were 0.29 without S9 mix and 0.77 with S9 mix. This difference in response according to the activation conditions is to be expected of a direct alkylating agent. The negative control did not cause differential killing of the 2 strains.
CONCLUSION	The notified chemical showed no evidence of damage to bacterial DNA under the conditions of the test.
TEST FACILITY	IRI (1987g)

8. ENVIRONMENT

No ecotoxicity to fish, *Daphnia*, or algae data were submitted, however estimations were done using the computer modelling software BIOWIN v4.00 and ECOSAR v0.99g, as detailed below.

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	HME-313
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I)
Inoculum	Activated sewage sludge from ten locations in Japan.
Exposure Period	28 Days
Auxiliary Solvent	Nil
Analytical Monitoring	BOD measured with a closed system oxygen consumption measuring apparatus; determination of dissolved organic carbon by a total organic carbon analysis; and determination of test substance by gas chromatography.
Remarks - Method	The test was validated by referencing to Aniline.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	62	7	41
14	77	14	81
21	88	21	83
28	94	28	84

Remarks - Results	The percentage biodegradation of notified chemical by BOD averaged 94%. The percentage biodegradation of notified chemical by TOC averaged 98%. The percentage biodegradation of notified chemical by GC average 100%. The percentage biodegradation of aniline calculated by the BOD values was 41% and 81% after 7 and 14 days, respectively. It is concluded that the test conditions were valid.
CONCLUSION	The notified chemical is classified as ready biodegradable.
TEST FACILITY	Kurume Research Laboratories (1993a)

The following estimations using BIOWIN v4.00 have been made by DEH, to support the test.

Linear Model Prediction .....Biodegrades Fast
Non-linear Model Prediction.....Biodegrades Fast
Ultimate Biodegradation Timeframe .....Weeks
Primary Biodegradation Timeframe.....Days-Weeks
MITI Linear Model Prediction.....Biodegrades Fast
MITI Non-linear Model Prediction.....Biodegrades Fast

8.1.2. Atmospheric Half-life

13.232 hrs (Estimated)

METHOD Estimation method – AOPWIN v1.91

8.2. Ecotoxicological investigations

The following have been estimated by DEH using ECOSAR v0.99g, using a log K_{OW} of 0.16, a water solubility of 8.25 x 10^4 mg/L and the equation for neutral organics.

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	HME-313
METHOD	Estimation using ECOSAR v0.99g
Exposure Period	96 hours
RESULTS	
LC50	4142 mg/L at 96 hours.
Remarks – Results	
CONCLUSION	The notified chemical is estimated to be only very slightly toxic to fish.

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	HME-313
METHOD	Estimation using ECOSAR v0.99g
Species	Daphnid
Exposure Period	48 hours
RESULTS	
LC50	3909 mg/L at 48 hours
Remarks - Results	
CONCLUSION	The notified chemical is estimated to be only very slightly toxic to daphnids.

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	HME-313
METHOD	Estimation using ECSAR v0.99g
Exposure Period	96 hours
Remarks - Method	
RESULTS	
EC50	2198 mg/L at 96 hours
Remarks - Results	
CONCLUSION	The notified chemical is estimated to be only very slightly toxic to algae.

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	HME-313
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated returned sludge of a sewage disposal plant.
Exposure Period	3 hours
Concentration Range	Nominal: 62.5 - 1000 mg/L
Remarks – Method	The EC_{50} value of the test material was calculated by semilogarithmic

	plot of the obtained inhibition percentages against the test material.
RESULTS	
EC50	>1000 mg/L
Remarks – Results	Up to and including the concentration of 1000 mg/L (nominal) the notified chemical had no significant inhibitory effects (<15%) on the respiration rate of activated sludge after the incubation period of 3 hours. The respiration rates of the control solution before and after the study and EC_{50} value of the standard material (3,5-dichlorophenol LC 26.1 mg/L) were in the acceptable range for the study.
CONCLUSION	The notified chemical does not significantly inhibit the respiration rate of activated sludge.
TEST FACILITY	Kurume Research Laboratories (1993b)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Environmental exposure of the notified chemical will result from the disposal of cartridges, printed-paper and any leaked ink containing the chemical during the use of the cartridges. The total import volume of the notified chemical will ultimately be either disposed of to landfill, incinerated or recycled with paper.

The notified chemical is moderately volatile, and therefore, some may dissipate into air from the paper, with an estimated half-life of 13.232 hrs. It is water-soluble and is expected to remain within the aquatic environment based on its Henry's Law constant of 1.69 x 10^{-10} atm-m^3/mole (log H –9.77), but will not readily hydrolyse in natural waters at environmental pH values. The low log K_{ow} (-0.56) is consistent with the high water solubility indicating a low affinity for the organic phase and component of soils and sediments. It can be highly mobile in soil due to high water solubility.

The notified chemical is readily biodegradable. Incineration of waste paper and sludge will destroy the compound with the generation of water vapour and oxides of carbon. Recycling may take place in a number of centres throughout Australia. During the paper recycling process, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. Trade sources estimate the washing process will recover 30-60% of the total amount of ink and it is generally assumed at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill. However, a greater proportion can be expected to remain in the aqueous phase due to the high water solubility of the notified chemical.

A predicted environmental concentration (PEC) in the aquatic environment is estimated below using a worst-case scenario where the entire import volume (the maximum of 1000 kg) of the notified chemical will be used on paper and 50% of the printed paper will be recycled with 60% of the chemical remaining in the aqueous phase during the recycling process. Under this scenario 300 kg of the notified chemical per year will be discharged to sewer and if assume that none is attenuated within the sewage treatment plants (STP), the daily release on a nationwide basis to receiving waters is estimated to be 0.82 kg/day.

Based on 30% of the notified chemical being released to the sewer, a Predicted Environmental Concentration (PEC) in the aquatic compartment can be estimated, as shown below.

Amount released to sewer:	300 kg
Population of Australia:	20.1 Million
Water use per person per day:	200 L
Number of days used:	365
PEC_{Sewer}:	300,000,000,000
	365x200x20,100,000
	= 0.20 µg/L
PEC_{River} (Dilution Factor = 1):	0.20 µg/L
PEC_{Ocean} (Dilution Factor = 10):	0.02 µg/L

The notified chemical is readily biodegradable. Its Henry's Law Constant of 1.69 x 10^{-10} atm-m^3/mole (log H –9.77) and log K_{ow} of 0.1626, were applied in the SIMPLETREAT model (European Commission 2003) for modelling partitioning and losses in STPs. The results indicate that when 300 kg of the notified chemical is released into the aqueous phase of a STP, 0% released to air through volatilisation, 0% partitioned to biosolids, 33% (100 kg) partitioned to water and 67% will be degraded. Therefore, the PECs of the notified chemical in effluent released, freshwater and marine water will be approximately 0.07, 0.07 and 0.007 µg/L, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this

volume is assumed to infiltrate and accumulate in the top 0.1 m of soil (density 1000 kg/m^3). Using these assumptions, irrigation with a concentration of 0.066 µg /L may potentially result in a soil concentration of approximately 6.6 x 10^{-4} mg/kg (1000L/m^2x 6.6 x 10^{-5} mg /L x 0.01 m^2/kg). Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 3.3 x 10^{-3} mg/kg (6.6 x 10^{-4} mg/kg x 5) and 6.6 x 10^{-3} mg/kg (6.6 x 10^{-4} mg/kg x 10), respectively.

Due to the low log P_{ow} and the high water solubility of the notified chemical, its potential for bioaccumulation is low in exposed aquatic organisms.

9.1.2. Environment – effects assessment

A predicted no effect concentration (PNEC - aquatic ecosystems) of 2.198 mg/L has been derived by dividing the end point value of 2198 mg/L (Green algae) by a worst-case scenario uncertainty (safety) factor of 1000. Use of this safety factor is also appropriate as no ecotoxicity data were provided and estimated ecotoxicity data has been used.

9.1.3. Environment – risk characterisation

	River	*Ocean*
PEC	0.20 µg/L	0.02 µg/L
PNEC	2.198 mg/L	2.198 mg/L
RQ (PEC/PNEC)	9 x 10^{-5}	9 x 10^{-6}

The worst case (no attenuation) RQ values (PEC/PNEC) derived for the aquatic environment are very low and well below 1 for both freshwater and marine waters, indicating no immediate concern to the aquatic compartment. Bioaccumulation is not expected from the diffuse use pattern and low import volume.

Based on the proposed use pattern the notified chemical is not expected to pose an unacceptable risk to the health of aquatic life.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

As the ink containing the notified chemical is imported in sealed cartridges packed in cardboard boxes typically plastic wrapped onto pallets, exposure to the notified chemical during transport and storage is expected to be very low. Accidental exposure through breach of packaging is possible but expected to be infrequent.

Office workers and service technicians may be exposed to the notified chemical through dermal contact and inhalation while changing spent cartridges, repairing printers or during normal printing processes. Service technicians are expected to have the highest occupational exposure, because they are likely to work with the printers for up to 8 h/day.

For all workers, due to the design of the cartridge dermal exposure is likely to occur only occasionally and to small quantities and as such dermal exposure is expected to be low. In addition, exposure is to be avoided because it would stain the skin and/or smudge the printed page. Exposure will be minimised by the use of disposable gloves by service personnel.

Inhalation exposure can occur during normal printing processes to vapour or aerosol of the notified chemical, one of the solvents in the ink. The notifier has advised that 0.06 g (60 mg) of ink is used for each printed page. As the ink contains <20% of the notified chemical, there is potential exposure to up to 12 mg of the notified chemical when each page is printed. The actual exposure is likely to be considerably lower than this, as normal air circulation would disperse such small quantities quickly, and some of the chemical would be trapped permanently or temporarily in the printed paper. Exposure of workers can vary depending on the type of ventilation, the amount of printing carried out in a short time, and the tendency of the chemical to be trapped in the paper. The use of one cartridge is likely to occur over a period of time. Therefore exposure is likely to be episodic rather than continuous. Exposure will be minimised

by placing printers in areas of adequate ventilation

If the notified chemical continued to be released into the air after the ink has dried, this could lead to further inhalation exposure. Due to the low volatility of the notified chemical at room temperature such release is expected to be slow and dispersed and therefore inhalation exposure is expected to be minimal. In addition, the notifier states that after drying the notified chemical is captured within the paper.

9.2.2. Public health – exposure assessment

Similarly to office workers, the public may be intermittently exposed to the notified chemical when replacing spent cartridges, and during use of printers. Dermal exposure to ink containing the notified chemical could occur accidentally but would be avoided because skin staining and/or smudging of the printed page. Inhalation exposure could also occur, but is expected to be episodic and limited by the small number of pages printed in a day.

Dermal exposure to the notified chemical in printed paper is expected to be negligible, as it will be bound in the structure of the paper. Although inhalation exposure to the notified chemical from printed paper could occur after the initial drying process, this is expected to be minimal due to the low volatility of the notified chemical.

Overall, exposure of the public is likely to be limited by the small quantity of notified chemical in each cartridge, the design of the cartridge, the controlled release during printing, relatively low vapour pressure and intermittent nature of exposure.

9.2.3. Human health – effects assessment

Acute toxicity.
The notified chemical was of low oral toxicity in an acute study in mice.

Irritation and Sensitisation.
Based on the results of the two skin irritancy studies, the notified chemical is considered to be non-irritating to skin except in situations where prolonged/repeated exposure (>24 hours) occurs. Even, in such exposure scenarios only very slight irritation is expected. The notified chemical is considered to be non irritating to eyes and unlikely to be a skin sensitiser.

Mutagenicity.
The notified chemical was non mutagenic to bacteria in an Ames test and did not induce damage to bacterial DNA under the conditions of a bacterial DNA damage test.

Hazard classification for health effects.
Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The risk to workers is expected to be low due to the limited predicted exposure and the expected low toxicity of the notified chemical.

9.2.5. Public health – risk characterisation

The risk to the public is expected to be low due to the limited predicted exposure and the expected low toxicity of the notified chemical.

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

10.1. Hazard classification

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

and

As a comparison only, the notified chemical is not classified as hazardous using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003). This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio of 9×10^{-5}, the chemical is not considered to pose a risk to the environment based on its reported use 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 inks containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). 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 notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees.
- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.
- 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.

Disposal

- The notified chemical should be disposed of by thermal decomposition in high temperature incinerators or to secure landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by physical containment and collection using absorbent material, with subsequent disposal by thermal decomposition in high temperature incinerators or to secure landfill.

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:

(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 any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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