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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

MJR-580

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FULL PUBLIC REPORT

MJR-580

1. APPLICANT

Epson Australia Pty Ltd of 70 Gibbes Street, Chatswood, NSW 2067 (ABN 91 002 625 783) has submitted a limited notification statement in support of their application for an assessment certificate for MJR-580.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the chemical composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: MJR-580

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Reddish brown lumpy solid

Melting point/boiling Point: Decomposed from approximately 225°C prior to melting and subsequent boiling.

Specific Gravity: 1.67 at 23.5°C

Vapour Pressure: 3.8×10^{-19} kPa at 25°C (see comments below)

Water Solubility: 93.1 mg/L at 20°C (see comments below)

Partition Co-efficient (n-octanol/water): Log P_{ow} = -2.11 at 20°C (see comments below)

Hydrolysis as a Function of pH:
pH 4 $t_{1/2}$ = 220 days
pH 7 $t_{1/2}$ = >1 year
pH 9 $t_{1/2}$ = >1 year (see comments below)

Adsorption/Desorption:

Soil	*K_{OC}*	*pH*	*% OC*
Wich brown earth	2,760	7.3	0.6
Bearsted brown earth	6,270	5.5	1.8
Wich brown earth	33,700	4.8	0.6

Dissociation Constant:	pK_{a1} = 3.84 pK_{a2} = 3.92 pK_{a3} = 8.85
Particle Size:	< 0.5% particles < 10µm; > 95% particles > 710µm
Flash Point:	Not flammable
Flammability Limits:	Not flammable
Autoignition Temperature:	360°C
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable
Surface Tension:	64.0mN/m at 19.5°C (see comments below)

3.1 Comments on Physico-Chemical Properties

All tests were performed on the notified chemical which includes 20% water as an impurity.

The vapour pressure was determined by EC Method 4A using a vapour pressure balance (Tremain and Bartlett 1995). The low value determined indicates that the chemical in the solid form is not volatile and, together with the moderate water solubility, gives a Henry's Law constant indicating it is unlikely to volatilise from water or moist soil surfaces.

All other tests were performed according to EEC and OECD test methods by Hogg and Bartlett (1995). The Flask method A6 of Commission Directive 92/69/EEC was used to determine that the water solubility of the notified chemical was moderate.

Hydrolysis as a function of pH was determined following method C7 of Commission Directive 92/69/EEC. The half-life (220 d) of the nonoxidising notified chemical is stable at the pH (4.4) of the imported aqueous ink solution.

The octanol-water partition coefficient was determined by the shake-flask method (Method A8 of Commission Directive 92/69/EEC) and the samples were analysed by HPLC.

The ionic nature and moderate water solubility of the compound are consistent with the low log P_{ow} and indicate very low affinity for the lipid component of soils and sediments. However, the log K_{oc} values in three sandy loam soils indicate the notified chemical was slightly mobile to immobile in soils as it binds strongly to positive charges. The three soils did not differ markedly in their particle size distribution and the methodology followed typical adsorption/desorption cycles, although a standard protocol was not referenced.

The dissociation constant data for the notified chemical show that the salts of the substance are likely to be dissociated within the ink preparation.

The surface tension of a 42.4 mg/L solution of the notified chemical in water was determined

following a variation of Method 5A of Commission Directive 92/69/EEC (Hogg and Barlett 1995). The value determined indicates that the chemical is not surface active.

4. PURITY OF THE CHEMICAL

Degree of Purity: Approximately 80%

Hazardous Impurities: None

Non-hazardous Impurities (> 1% by weight):

Chemical name:	Water
Weight percentage:	20.0%
CAS No.:	7732-18-5

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as an ink pigment and imported in 10-20mL ink-jet printer cartridges. The concentration of notified chemical in inks within the imported cartridges is 2-4%. Less than one tonne of the notified chemical will be imported annually for 5 years.

6. OCCUPATIONAL EXPOSURE

Import, Transport and Storage

MJR-580 will be imported in ready to use sealed ink-jet printer cartridges in pasteboard boxes. No reformulation or repackaging will take place. Hence, occupational exposure is not expected during transport and storage except in the event of accident breakage of the boxes and cartridges.

End Use - Customer Sites

Occupational exposure to MJR-580 will occur primarily to printer service personnel and office workers.

As the chemical is contained in a sealed cartridge, exposure predominantly via the dermal route is expected to be minimal during normal handling and replacement of printer cartridges by service technicians or printer users. Exposure may occur also in the event of a cartridge leak. Inhalation exposure to vapours released during the printing process would be negligible. Overall, the potential exposure would be low due to the small quantities of notified chemical present within the cartridge ink.

Dermal exposure may occur upon handling printed matter. However, only very small quantities of notified chemical would be present per sheet of paper and it would not be

available for exposure as it is fused and fixed to the printed surface.

The MSDS states that skin and eye protection are required when opening cartridges.

7. PUBLIC EXPOSURE

Exposure of the public as a result of transport and disposal of the ink products containing the notified chemical is assessed as being negligible. Ink products containing the notified chemical are fully contained within inkjet cartridges that are sold to the public and are inserted directly into inkjet printers after purchase. Dermal contact with ink deposited onto paper is possible, but public exposure via this route is expected to be low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Environmental exposure will result from the disposal of printed paper (estimated at 95%) and discarded cartridges (5%) as well as the possibility of accidental leakage of the cartridges during use.

Ink residues contained in the emptied cartridges are expected to remain within these containers, although release could occur from deterioration of the discarded spent cartridge. This could result in the disposal of <50 kg per annum to landfill in the fifth year of use, with release being widespread.

Release of the ink solution to the environment is not expected under normal use as the ink cartridge is designed to prevent leakage. However, in the case of leakage, the ink will be wiped up and the absorbent material presumably disposed of in landfill.

8.2 Fate

Some waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified substance. Incineration of waste paper will destroy the compound with the generation of water vapours, oxides of carbon, nitrogen and sulfur and sodium containing compounds.

The notifier estimates about 20% of the ink printed on paper will enter the paper recycling process. During such processes, 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 are expected to go to trade waste sewers. The notifier expects the washing process to recover 30-60% of the total amount of ink and therefore at least 30% of the MJR-580 in the paper has the potential to leach to groundwater at landfills. However, the immobile nature (as shown by the K_{oc} values) indicates strong binding to soil and no entry to groundwater despite its moderate water solubility.

A biodegradation study was conducted using the notified chemical which includes 20% water as an impurity; the results obtained for this mixture are considered scientifically valid. The test was conducted according to OECD TG 301C – Ready Biodegradability, Modified MITI

test (Yoshida, 1995).

Activated sludge, obtained from the Chemical Biotesting Centre in Japan, was mixed with the test substance or reference material (aniline) at final concentrations of 100 mg/L for the chemicals and 30 mg/L for the activated sludge. The biodegration of aniline calculated from BOD values was 58% after 7 d, indicating the test conditions were valid.

Result: After 28 days at 25±1°C, the biodegradation of the test substance as measured by HPLC was <2.6%. Measurement of Biochemical Oxygen Demand (BOD) and Dissolved Organic Carbon (DOC) indicated that there was no biodegradation under the conditions of the test.

Conclusion: The test substance was considered not readily biodegradable under the conditions of the modified MITI test.

The substance is not expected to bioaccumulate due to its moderate water solubility and low log Pow value.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of MJR-580.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000mg/kg	Allen (1995a)
acute dermal toxicity	rat	LD_{50} > 2000mg/kg	Allen (1995b)
skin irritation	rabbit	Not irritating	Allen (1995c)
eye irritation	rabbit	Slightly to moderately irritating	Allen (1995d)
skin sensitisation	guinea pig	Not sensitising	Pels Rijcken (1996)

9.1.1 Oral Toxicity (Allen, 1995a)

Species/strain:	Rats, Sprague-Dawley CD
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Gavage
Test method:	OECD TG 401
Mortality:	None
Clinical observations:	Red staining of fur was noted in all male animals up to 1 day after administration, 2 males up to 4 days after

	administration and 1 male up to 6 days after administration. All animals showed bodyweight gain during the study.
Morphological findings:	No abnormalities were noted at necroscopy.
LD_{50}:	> 2000mg/kg (limit test)
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Allen, 1995b)

Species/strain:	Rats, Sprague-Dawley
Number/sex of animals:	5 males, 5 females
Observation period:	14 days
Method of administration:	Single 24 hour application of notified chemical to clipped, intact skin under semi-occlusive dressing.
Test method:	OECD TG 402 (limit test)
Mortality:	None
Clinical observations:	No signs of systemic toxicity were observed.
Morphological findings:	No abnormalities were observed at necroscopy.

Draize scores:

No animal showed positive irritation responses at any time during the study.

LD_{50}:	> 2000mg/kg
Result:	The notified chemical was of low dermal toxicity in rats.

9.1.3 Inhalation Toxicity

Data were not provided.

9.1.4 Skin Irritation (Allen, 1995c)

Species/strain:	Rabbit, New Zealand White
Number/sex of animals:	3 males
Observation period:	72 hours
Method of administration:	Single 4 hour application of notified chemical (0.5g) to

clipped, intact skin under semi-occlusive dressing.

Test method: OECD TG 404

Draize scores:

No animal showed positive irritation responses at any time during the study.

Comment: Pink staining was noted at all treated skin sites during the study.

Result: The notified chemical was not irritating to the skin of rabbits.

9.1.5 Eye Irritation (Allen, 1995d)

Species/strain: Rabbit, New Zealand White

Number/sex of animals: 2 males, 1 female

Observation period: 21 days

Method of administration: 0.1mL of test substance instilled into the conjunctival sac of the right eye.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

Time after instillation

Animal	***1 hour***			***24 hours***			***2 days***			***3 days***			***7 days***			***14 days***			***21 days***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
1	[1]d		4	0		0	0		0	0		0	0		0	0		0	-		-
2	d		4	1		2	1		1	0		0	0		0	-		-	-		-
3	d		4	4		1	4		1	4		1	2		1	1		1	0		0
Iris																					
1	?s			?s			?s			?s			?s			0			-		
2	?s			?s			?s			?s			0			-			-		
3	?s			?s			?s			?s			?s			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	?s	2	3	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	-	-	-
2	?s	2	3	2	2	2	2	1	0	1	1	0	0	0	0	-	-	-	-	-	-
3	?s	2	3	2	2	1	2	1	0	1	1	0	0	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

d = dulling of corneal surface ?s = unable to evaluate due to staining
- = observation not performed

Comment: Red-coloured staining was noted in all treated eyes at 1, 24, 48 and 72 hours and 2 treated eyes at 7 days. All animals had recovered by 14 days. Eye lesions were observed but were insufficient for hazardous classification.

Result: The notified chemical was slightly to moderately irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Pels Rijcken, 1996)

Species/strain: Guinea pig, Dunkin Hartley Crl: (HA)BR

Number of animals: 10 females - treatment; 5 females - control

Induction procedure: Three pairs of intradermal injections (0.1mL/site) in the clipped scapular region:

Test group:

Day 1	• Freund's Complete Adjuvant (FCA) 50:50 with water • Test substance 10% in water • Test substance 20% in water in FCA 50:50
Day 7	• Clipped area rubbed with 10% sodium-dodecyl-sulphate in Vaseline
Day 8	• Clipped area treated with patch containing 0.5mL of 50% test substance in water held under semi-occlusive dressing.

Control group:

Day 1	• Freund's Complete Adjuvant (FCA) 50:50 with water • Water vehicle • Water, FCA 50:50
Day 7	• Clipped area rubbed with 10% sodium-dodecyl-sulphate in Vaseline
Day 8	• Clipped area treated with patch containing 0.5mL of water vehicle held under semi-occlusive dressing.

Challenge procedure:

Day 22	Clipped area treated with Square chambers containing 0.05ml of 10%, 25% and 50% test substance in water held under semi-occlusive dressing.
Day 23	To remove test substance staining and facilitate scoring, the test sites were treated with a depilatory cream for 4 minutes.

Test method: OECD TG 406 – Magnusson and Kligman maximisation

test

Challenge outcome:

Challenge concentration	Test animals		Control animals	
	*24 hours**	*48 hours**	*24 hours*	*48 hours*
10%	0**	0	0	0
25%	0	0	0	0
50%	0	0	0	0

* time after patch removal
** number of animals exhibiting positive response

Comment: One animal was removed from the study on day 11 after displaying breathing difficulties and dark coloured eyes. At necroscopy, microscopic examination revealed dark red spotting of the lungs and ascites in pericardium indicating acute pneumonia. One animal was found dead on day 16. Macroscopic examination also revealed dark red patches in lungs.

Result: The notified chemical was not sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Otsuka 1996)

Species/strain: Rats, Crj:CD (SD)

Number/sex of animals: 6/sex/dose

Method of administration: Oral (gavage)

Dose/Study duration: 0 (control), 40 (low), 200 (mid), 1000 (high) mg/kg/day for 28 days.
14 day recovery groups for controls and 1000 mg/kg/day.

Test method: OECD TG 407

Clinical observations:
No deaths occurred during the study. Salivation was observed in some males in the high dose group from day 24 to 27. Body weights in males in the mid and high dose groups were significantly increased on days 27 and 28.

Food consumption increased in the low dose group between weeks 2 and 4 and in the high dose group between weeks 1 and 4.

Clinical chemistry/Haematology
No significant changes in haematological parameters were observed in either males or females. In non-recovery subgroups, creatinine levels were increased significantly in low

and mid dose group males but the changes were within normal limits, not dose dependent and so considered not related to the test substance. Inorganic phosphorus was increased significantly in high dose males and calcium was increased significantly in high dose females.

In recovery subgroups, no significant changes were observed in male animals. In high dose females, GPT and albumin levels and albumin/total protein ratios were significantly reduced. However, because these were within normal ranges and not observed in non-recovery subgroups, they were considered unrelated to the test substance.

Pathology:
In non-recovery subgroups, liver weights were significantly increased in mid-dose males. However, there were no significant differences in relative organ weights, the changes lacked dose-dependency and so were regarded as unrelated to the test substance. Mid and high dose females showed significant increases in kidney weights. Relative testicular weights were significantly decreased in low dose males.

In all high dose animals, a reddish staining was observed in the kidneys. In this same group, renal enlargement was observed in a single male. Another male animal showed a recessed area in the brain with unilateral ventricular enlargement, fibrosis of the choroid plexus with calcification and brown pigmentation. Dark red or grayish-white spots in the liver were noted in one male and one female animal.

In recovery subgroups, adrenal weights and relative adrenal and testes weights were decreased significantly in high dose males. In this high dose group, another male showed pale red stained kidneys and another showed dilation of the renal pelvis.

Histopathology:
In non-recovery subgroups, the kidneys of all males of every dose group (including 3 in the control group) showed eosinophilic granules in the proximal tubular epithelium. The number of granules was considerably higher in the high dose group and was therefore considered to be a treatment-related effect.

In recovery subgroups, eosinophilic granules were observed in several control and high dose animals. Incidence and severity of change was similar in both dose groups. Eosinophilic bodies, atrophy or regeneration of cortical tubules, renal calcification, lymphocyte infiltration, pelvic dilation and focal dilation of tubules were noted also in several animals of both control and high dose groups.

Comment:
Subtle treatment-related changes could be observed in both sexes. Increased food consumption and weight gain were observed at the high dose in both sexes and in mid dose males. At this high dose, both sexes also displayed changes in clinical chemistry and histological changes in the kidney. Increased food consumption and weight gain were observed also in mid dose males and mid dose females also showed increased kidney weight. No changes related to the test substance were observed in either sex at the lowest dose.

Result:

Based on increases in kidney weight observed at the mid dose (200mg/kg/day), no-adverse-effect-level (NOAEL) of 40mg/kg/day was established for the test substance.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Machigaki, 1995)

Strains:	*Salmonella typhimurium* TA98, TA100, TA1535, TA1537; *Escherichia coli* WP2 uvrA
Metabolic activation:	5,6-benzoflavone-induced rat liver microsomal fraction S9
Concentration range:	313, 625, 1250, 2500, 5000μg/plate
Test method:	OECD TG 471, 472
Comment:	No toxicity was observed at any concentration of test substance. Precipitation of test substance was observed at 5000μg/plate.
Result:	The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in Cultured Peripheral Human Lymphocytes (van de Waart, 1996)

Cells:	Peripheral human lymphocytes
Metabolic activation system:	Aroclor 1254-induced rat liver microsomal fraction S9
Test method:	OECD TG 473
Dosing schedule:	

Metabolic Activation	***Experiment/ Study Number***	***Test concentration (μg/mL)***	***Controls***

-S9	Initial study	Treatment time = 3 hours/24 hour harvest 333*, 1000* and 1778* µg/mL Treatment time = 24 hours/24 hour harvest 100, 333*, 562, 1000*, 1334* and 1540 µg/mL Treatment time = 48 hours/48 hour harvest 333*, 1000*, 1334*, 1540 and 1778 µg/mL	Positive: Mitomycin C Negative: DMSO vehicle
	Confirmation study	Treatment time = 24 hours/24 hour harvest 333*, 562*, 1000*, 1334 and 1400 µg/mL	
+S9	Initial study	Treatment time = 3 hours/24 and 48 hour harvest 333*, 1000* and 1778* µg/mL	Positive: Cyclophosphamide Negative: DMSO vehicle
	Confirmation study	Treatment time = 3 hours/24 hour harvest 333*, 1000* and 1778* µg/mL	

EMS - ethyl methanesulphonate
CP - cyclophosphamide
DMSO – dimethylsulphoxide
* - cultures selected for metaphase analysis

Comment:

The chromosome aberration assay was conducted in duplicate. A preliminary range-finding test established a maximum concentration of 1778µg/mL at which test substance precipitation in culture medium was observed.

In the absence of metabolic activation, the test substance failed to induce significant increases in chromosome aberrations. With metabolic activation, a statistically significant increase in cells with chromosome aberrations was observed with 1778µg/mL test substance. However, these were observed in one experiment only, were not dose related, were of simple, non-exchange type aberrations and were of statistical significance only when gaps were included. The aberrations observed were not considered biologically relevant.

Result:

The notified chemical was non clastogenic under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

In acute toxicity tests, the notified chemical was shown to possess very low oral and low dermal toxicity with a rat LD_{50} for both tests established at >2000mg/kg.

A skin irritation test in rabbits showed that the notified chemical was not irritating. An eye irritation study showed the notified chemical to be slightly to moderately irritating. In a skin sensitisation study, the notified chemical did not induce allergic responses in guinea pigs.

A 28-day repeated dose oral toxicity study in rats established a NOAEL of 40mg/kg/day.

A mutagenicity assay in bacteria and chromosome aberration assay in human peripheral lymphocytes showed the notified chemical to be non mutagenic and non-clastogenic respectively *in vitro*.

On the basis of these toxicological tests and according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), the notified chemical cannot be classified hazardous.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier supplied ecotoxicity studies on the notified chemical, the results of which are summarised in the following table. The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of Good Laboratory Practices.

Test	Species	Concentration (mg a.i./L)	Results (mg a.i./L)
Fish Acute Toxicity (Static Renewal) (OECD TG 203)	Rainbow trout (*Oncorhynchus mykiss*)	38.6 (measured)	96-h LC50 > 38.6 96-h NOEC = 38.6
Acute Toxicity - Immobilisation (Static Test) (OECD TG 202)	Water Flea (*Daphnia magna*)	38.4 (measured)	48-h EC50 > 38.4 48-h NOEC = 38.4
Algal Growth Inhibition (Static Test) (OECD TG 201)	Green Alga (*Scenedesmus subspicatus Chodat*)	Up to 0.69 (measured)	72-h EbC50 = 0.43 72-h ErC50 = 0.34 NOEC = 0.037
Respiration Inhibition (OECD TG 209)	Activated Sludge - Aerobic Waste Water Bacteria	793	3-h EC50 > 793 LOEC = 793

* NOEC - no observable effect concentration

Fish (Wetton and Bartlett 1995a)

Rainbow trout juveniles (mean length 5.2 cm, mean mass 1.65 g) were exposed to mean measured concentrations of 38.6 mg a.i./L (reported as the limit of solubility although the water solubility of the notified chemical is 93.1 mg/L) for 96 h. Treatments were replicated

twice (10 fish each) with a single control of 10 fish. The static test solutions were renewed daily and held at 14˚C and 16 h light. As no mortalities or sublethal effects were observed in any test vessel, the 96-h LC50 and NOEC were >38.6 mg a.i./L indicating no toxicity to trout up to the limit of solubility.

Aquatic Invertebrates (Wetton and Bartlett 1995b)

Neonate *Daphnia magna* (≤24 h old) were exposed to the test substance at a mean measured concentration of 38.4 mg a.i./L. The four replicate treatments and duplicate controls (containing 10 daphnids each) were held static at 21˚C and 16 h light for 48 h. No immobilisation or adverse effects were observed in any test vessel giving a 48-h EC50 and NOEC of >38.4 mg a.i./L. Therefore the notified chemical is not toxic to daphnids up to its limit of solubility.

Algal Inhibition Test (Mead and Bartlett 1995)

Algae were exposed to the test substance at measured (by HPLC) concentrations up to 0.69 mg a.i./L for 72 h at 24±1˚C under constant illumination. The test substance was dissolved directly in culture medium. Three replicate test flasks were prepared for each concentration and control. No abnormalities were detected following microscopic inspection of all cultures except clumping of cells in the highest treatment. Both biomass and growth of *Scenedesmus subspicatus* were adversely affected by the test substance. Based on measured concentrations, the 72-h EbC_{50} (biomass) and ErC_{50} (growth rate) were 0.43 and 0.34 mg a.i./L, respectively, with a NOEC of 0.037 mg a.i./L. This is considered highly toxic. A 72-h regrowth experiment found that cells from the highest treatment and control reproduced when placed in clean medium, but the extent of growth was not stated. Therefore the effect of the notified chemical on algae is presumably algistatic, not algicidal.

Microorganisms (Mead 1995)

Activated sewage sludge was exposed to the test material at 1,000 mg/L for 3 h with the addition of a synthetic sewage as a respiratory substrate. The notified chemical was dissolved directly in water. Three replicate test flasks were prepared with duplicate controls. The reference material, 3,5-dichlorophenol was prepared at 3.2 and 32 mg/L with no replicates. Oxygen consumption rates for test and reference flasks were determined after 30 minutes and 3 h at 21˚C. No significant effect on respiration (oxygen consumption rates and percent inhibition) was observed at any of the test concentrations. The validation criteria for control respiration rates and reference material percent inhibition were satisfied. The effect of the test substance on the respiration of activated sludge gave a 3-h EC_{50} of >1,000 mg/L or >793 mg a.i./L.

Conclusion

The notified chemical caused no adverse effects, mortality or growth inhibition on fish and daphnia at the limit of solubility and would be considered practically non-toxic to these organisms. However, the notified chemical was highly toxic to algae.

Aerobic microbial activity was unaffected following exposure to the notified chemical.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will enter environmental compartments indirectly by disposal of waste

paper (for recycling, to landfill or for incineration) and by direct release from discarded spent cartridges at landfill sites. Based on the import volume, method of packaging and low concentration of the notified chemical in ink (2-4%), release of the notified chemical to the environment is expected to be low but widespread.

Abiotic or slow biotic processes would be largely responsible for the degradation of the notified chemical as it was not readily biodegradable. Although the low octanol-water partition coefficient and moderate water solubility indicate the notified chemical will be predominantly distributed in water, the high log K_{oc} values indicate it is only slightly mobile to immobile in soils as it binds strongly to positive charges.

Any released chemical is not expected to adversely affect aquatic organisms except algae. However, the stong binding to soil/sediment and presumed algistatic (not algicidal) effect is expected to limit the exposure of algae to an acceptable level. Although not specifically relevant to the use pattern and disposal as described, disposal of the notified chemical to sewage treatment plants is not expected to adversely affect aerobic sewage microorganisms. In addition, bioaccumulation is not expected as the log P_{ow} indicates low lipid solubility and the large molecular weight suggests inhibited passage through cell membranes. On the basis of the available information, the overall environmental hazard of the notified chemical is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

Toxicological data indicate that MJR-580 has low acute oral and dermal toxicity. It is slightly to moderately irritating to eyes but not irritating to skin and is not a skin sensitiser. MJR-580 was neither mutagenic nor clastogenic in bacteria and human peripheral lymphocytes, respectively.

In a repeated dose toxicity test, a no-adverse-effect-level (NOAEL) of 40mg/kg/day was established, based on increases in kidney weight at higher doses.

Based on the data provided, MJR-580 would not be classified hazardous according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Occupational Health and Safety

Transport and storage workers will be only be exposed to MJR-580 in the event of an accident or damage to packaging. The occupational health risk to these workers is negligible, considering the low quantities (2-4%) in ink jet printer cartridges and the low toxicological hazard represented by the notified chemical.

The main exposure to MJR-580 will be to service personnel who will change printer cartridges and come into contact with internal printer componentry that may be contaminated with ink. The design of the cartridge is such that skin contact to the notified chemical should be minimal during replacement.

Office workers may come into contact with MJR-580 under normal circumstances during the

routine replacement of spent printer cartridges or clearing paper jams. Exposure to MJR-580 is not expected to occur once the ink containing the chemical is bound to paper. The low concentration of notified chemical in the ink and low toxicological impact of notified chemical renders the health risk for service personnel and end users low.

The product label contains instructions on replacing printer cartridges.

Public Health

Exposure of the public as a result of transport and disposal of products containing the notified chemical is assessed as negligible. Dermal contact with ink deposited onto paper is a possible route of public exposure but given the low concentration of the notified chemical and the low toxicological hazard posed by the notified chemical, the risk to public health is expected to be very low.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical, the following guidelines and precautions should be observed:

- Protective eyewear, clothing and gloves should be worn when handling the notified chemical;
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

No special precautions are required for the notified chemical when used at low quantities in ink-jet printer cartridges. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed:

- Service personnel should wear cotton or disposable gloves when removing spent printer cartridges containing the notified chemical or when servicing printers.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/ Standards New Zealand, 1998), or other internationally acceptable standards.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

Allen DJ (1995b) MJR-580(H): Acute dermal toxicity (limit test) in the rat. SPL project number: 388/125. Safepharm Laboratories Limited, Derby, UK.

Allen DJ (1995c) MJR-580(H): Acute dermal irritation test in the rat. SPL project number: 388/126. Safepharm Laboratories Limited, Derby, UK.

Allen DJ (1995d) MJR-580(H): Acute eye irritation test in the rabbit. SPL project number: 388/127. Safepharm Laboratories Limited, Derby, UK.

Allen DJ (1995a) MJR-580(H): Acute oral toxicity (limit test) in the rat. SPL project number: 388/124. Safepharm Laboratories Limited, Derby, UK.

Hogg AS & AJ Bartlett (1995) MJR-580(H): Determination of general physico-chemical properties. PL Project Number: 388/121. Safepharm Laboratories Ltd, Derby, UK.

Machigaki E (1995) Bacterial reverse mutation study of MJR-580(H). Study No. 5L635. General Testing Centre, Japan Oilstuff Inspectors Corporation, Hyogo, Japan.

Mead C (1995) MJR-580(H): Assessment of the inhibitory effect on the respiration of activated sewage sludge. SPL Project Number: 388/132. Safepharm Laboratories Ltd, Derby, UK.

Mead C & AJ Bartlett (1995) MJR-580(H): Algal inhibition test. SPL Project Number: 388/131. Safepharm Laboratories Ltd, Derby, UK.

NOHSC (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Canberra, Australian Government Publishing Service.

NOHSC (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, AusInfo.

Otsuka M (1996) Twenty-eight day repeated dose oral toxicity study of MJR-580(H) in rats. Bio-Medical Research Laboratories Co Ltd, Kanagawa, Japan.

Pels Rijcken WR (1996) Assessment of contact hypersensitivity to MJR-580 (H) in the albino guinea pig (maximisation test). Notox BV, Hertogenbosch, The Netherlands.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/ Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia/Standards Association of New Zealand

Tremain SP & AJ Bartlett (1995) MJR-580(H): Determination of vapour pressure. SPL Project Number: 388/123. Safepharm Laboratories Ltd, Derby, UK.

van de Waart EJ (1996) Evaluation of the ability of MJR-580(H) to induce chromosome aberrations in cultured peripheral human lymphocytes (with independent repeat). Notox BV, Hertogenbosch, The Netherlands.

Wetton PM & AJ Bartlett (1995a) MJR-580(H): Acute toxicity to rainbow trout (Oncorhynchus mykiss). SPL Project Number: 388/129. Safepharm Laboratories Ltd, Derby, UK.

Wetton PM & AJ Bartlett (1995b) MJR-580(H): Acute toxicity to Daphnia magna. SPL Project Number: 388/130. Safepharm Laboratories Ltd, Derby, UK.

Yoshida K (1995) Ready biodegradability test of MJR-580 (H). MSI Report No. 5B251G. Mitsubishi Chemical Safety Institutes Ltd.

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol. Exp. Ther. 82 : 377-390.

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.