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23 April 2020

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

MJM-80

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Epson Australia Pty Ltd of 70 Gibbes Street CHATSWOOD NSW 2067 (ACN 002 625 783) has submitted a Limited Notification statement in support of their application for an assessment certificate for MJM-80

2. IDENTITY OF THE CHEMICAL

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

Marketing Name:	MJM-80
Other Names:	AKDE-2

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Purple powder
Boiling Point: (Safepharm Laboratories Limited 1999j)	> 360°C
Specific Gravity: (Safepharm Laboratories Limited 1999i)	1.68 g/cm^2
Vapour Pressure: (Safepharm Laboratories Limited 2000c)	2.6 x 10^{-16} kPa
Water Solubility at 20°C: (Safepharm Laboratories Limited 1999j)	42.5 % w/w – see comments below (readily soluble)
Partition Co-efficient (n-octanol/water): (Safepharm Laboratories Limited 1999j)	Log P_{ow} <- 3.85

Surface Tension at 21°C: (Safepharm Laboratories Limited 1999i)	71.7 mN/m
Hydrolysis as a Function of pH:	Not determined – see comments below.
Adsorption/Desorption:	Log K_{oc} <-0.982 (by QSAR)
Dissociation Constant:	Not determined – see comments below.
Flash Point:	Not applicable to a solid.
Flammability Limits: (Safepharm Laboratories Limited 1999h)	Not highly flammable
Autoignition Temperature: (Safepharm Laboratories Limited 2000b)	350°C
Explosive Properties:	Test not conducted, not but there is no cause for concern over explosivity.
Reactivity/Stability:	Expected to be stable – see comments below.
Particle Size: (Safepharm Laboratories Limited 1999i)	Proportion with: < 100 µm = 32.2%; < 10 µm = 6.03%.

Comments on Physico-Chemical Properties

Tests were performed according to corresponding EC and OECD test guidelines (EC 1992) (OECD 1995-1996,) at Safepharm Laboratories Limited UK. These facilities comply with the OECD principles of good laboratory practice (GLP) and full test reports were submitted. All tests were performed on the notified chemical.

The boiling point of the notified chemical was not determined because of its high melting point.

The vapour pressure was determined by EEC Method 4A using a vapour pressure balance. The low value determined indicates that the chemical in solid form is not volatile and given the high water solubility, the compound is unlikely to be volatile from water (Lyman 1982).

The ready water solubility of the chemical meant that samples could not be prepared as recommended in the guidelines and water solubility was estimated from visual inspection using a modified flask method based on EC Method 6A.

Hydrolysis as a function of pH was not determined as the chemical structure is not prone to hydrolysis. The notified chemical is imported in an aqueous ink solution suggesting it is stable.

The octanol/water partition co-efficient was determined using the shake-flask method (EC Method A8) and HPLC.

The ionic nature and water solubility of the compound is in accord with the low values for log P_{ow} indicating very low affinity for the organic component of soils and sediments. However, it was not possible to obtain experimental values for log K_{oc} and the notifier estimated this parameter from log P_{ow} using Quantitative Structure Activity Relationship (QSAR) analysis. The equation used was not specified, but was reportedly one recommended by the OECD. The resultant log K_{oc} was -0.982. This agrees the properties stated above and the new chemical is unlikely to be adsorbed to soil or sediment.

The notifier did not supply dissociation constant data for the notified chemical and claimed that the salts of the substance are likely to be dissociated within the ink. As the pKa for sulphurous acid is low, 1.81 (Weast 1976) the degree of dissociation within an aqueous solution is likely to be high as suggested by the notifier.

The surface tension of a 1 g/L solution of the notified chemical in water was determined following a variation of EC Method 5A and indicates that the chemical is not surface active.

The notified chemical does not have oxidising properties based on consideration of structure and experience in use. It is not known to be incompatibile with other substances.

The chemical is considered to be stable and there are no known hazardous decomposition products. The chemical is combustible and will burn evolving noxious fumes eg. carbon, nitrogen, sulfur oxides and sodium containing compounds.

4. PURITY OF THE CHEMICAL

Degree of Purity: Very high.
(Exact details have been claimed confidential)

Hazardous Impurities: None

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

Chemical name: Various unidentified organic compounds
Weight percentage: <5%.
(Exact details have been claimed confidential)

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured or reformulated in Australia but will be imported as an aqueous ink at 5 % maximum by weight. The ink is contained within plastic cartridges for direct use in computer colour printers. Cartridges hold about 10 to 15 g of ink.

The ink cartridges will be inserted into colour printers and the ink dispersed onto printed paper. The pigment loading on a given page will vary considerably due to wide variances in print density used. The amount of residual ink in spent cartridges is estimated at less than 1 g.

The estimated annual import volume in the first year is less than 100 kg and by the fifth year less than 200 kg.

6. OCCUPATIONAL EXPOSURE

The notified chemical is a component (maximum 5%) of an imported aqueous ink. No reformulation or repackaging will take place. Hence, no exposure to the notified chemical in the toner is expected during transportation and storage other than from accidental spillage.

Occupational exposure to the ink could be experienced by trained technicians during printer servicing, and office or printing staff during cartridge exchange (when a sealing tape is removed prior to insertion) and removal of paper jams. Cartridge exchange is done according to the manufacturers instructions.

During cartridge exchange, skin contact could occur in the event of a container leak or spill. However, this is expected to occur infrequently if at all. More commonly, occasional skin contact to ink residues inside the machine may occur during machine servicing or paper feed problems.

When in use, the ink is completely sealed in the developing unit of the printer.

Skin contact may occur upon handling printed matter with the ink applied. However, it becomes heat fixed once applied to the printed surface. These considerations indicate there would be no exposure to the notified chemical during the handling of printed materials.

7. PUBLIC EXPOSURE

Exposure of the general public to MJM-80 may occur through clearing paper jams in the printers and encountering ink residues or as the result of an accidental spill. In the event of a spill, the notified chemical should be collected mechanically and disposed of in accordance with local/national legislation. It should be prevented from contaminating the ground water system and from entering drains. The public should be evacuated from the area of the spill and kept away from and upwind of the spill/leak.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Environmental exposure will result from accidental leakage of the cartridges during use and disposal of printed paper and discarded cartridges.

Ink residues would remain within the emptied cartridges until the discarded cartridge deteriorated. This could result in the release of up to 15 kg per annum to landfill.

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 most probably disposed of to 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.

Printed paper may also be recycled. The notifier has provided no data on the likely behaviour of the chemical during paper recycling. During such processes, waste paper is repulped using 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 ready water solubility of the notified chemical suggests that any released to the aquatic compartment, for example from de-inking of paper, will remain in solution. The calculated adsorption/desorption co-efficient suggests that the notified chemical disposed of to landfill, may leach into the aquatic compartment. The residues of the ink will be rapidly diluted due to the high water solubility.

Biodegradation and Bioaccumulation

Biodegradation and bioaccumulation studies were conducted following OECD guidelines and in compliance with GLP standards. The tests were done on a near identical substance (a mixture of the free acid and sodium salt of the dye) to the notified chemical. The results obtained for the analogue mixture are considered scientifically valid for the notified chemical as the only difference is a presence of the ammonium salt within the notified chemical.

8.3.1 Biodegradation Study (Kurume Research Laboratories 1999b)

Sample: Activated sludge was prepared from samples collected from ten sites in Japan (both return sludge from sewage plants, and surface water and surface soil from river or bay sites), to which synthetic sewage was added.

Experiment Design: The test substance and reference material (aniline) were both tested in triplicate to a total organic content of 100 mg/L. The percentage biodegration of aniline calculated from Biochemical Oxygen Demand (BOD) values was 67% and 71% after 7 and 14 days respectively, indicating that the test conditions were valid.

Test Method: Method for Testing the Biodegradability of Chemical Substances by Microorganisms stipulated in the Testing Methods for New Chemical Substances. This test method is similar to OECD TG 301C – Ready Biodegradability.

Result: Measurement of BOD and Total Organic Carbon (TOC) analysis indicated that there was no biodegradation under the conditions of the test. After a cultivation period of 28 days the percentage biodegradation of the test substance as measured by HPLC was 1%.

Conclusion: The test substance was not considered readily biodegradable by microorganisms under the conditions of the test.

8.3.2 Bioaccumulation Study (Kurume Research Laboratories 1999a)

The substance is not expected to bioaccumulate due to the high molecular weight of the components, ready water solubility and low log P_{ow}. A bioaccumulation test was performed following OECD guidelines and in compliance with GLP standards.

Species Carp (*Cyprinus carpio*)

Experiment Design:
In a 56-day bioaccumulation test, test fish were exposed to the test substance in water at nominal concentrations of 0, 0.852 (Level 1) or 0.0852 (Level 2) mg/L. The test groups and control group comprised 11 and 5 fish, respectively. The test water was supplied *via* a flow through system and tested twice weekly for test substance concentration and dissolved oxygen. Each average concentration of test substance in test water was measured to be greater than 90% of each of the nominal concentrations. Fish were observed twice daily for the duration of the study with no abnormality in behaviour or appearance noted at any observation time. In weeks 2, 4, 6 and 8, two fish from each test concentration were analysed for test substance. The concentration of test substance in each fish was below the minimum detection limit. Therefore, the Bio-Concentration Factor (BCF) in fish was estimated by extrapolation. As no bioaccumulation was observed during the study, depuration was not tested.

Test Method: Similar to OECD TG 305.

Result: The BCF is estimated to be less than 34.

Conclusion: Based on the BCF, the test substance is not prone to bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

The following toxicological investigations were performed according to corresponding EC and OECD test guidelines (EC 1992) (OECD 1995-1996). The tests were conducted at facilities that comply with the OECD principles of good laboratory practice and full test reports were submitted.

Data on the notified chemical were provided for investigations into acute toxicity. The test substance used in the 28-day repeat dose study is the free acid form of the notified chemical. The test substance used for the genotoxicity assays is a near identical chemical to the notified chemical - it differs from the notified chemical by the absence of an ammonium sodium salt. The data on the analogous chemicals is accepted for the assessment of the notified chemical as it is considered that the counterion present either on the notified chemical or the analogue substance would not contribute significantly to any toxic effects observed with the free acid form alone.

9.1 Acute Toxicity

Summary of the acute toxicity of MJM-80

Test	*Species*	*Outcome*
Acute oral toxicity	Rat	Estimated LD_{50} > 2 000 mg/kg
Acute dermal toxicity	Rat	LD_{50} > 2 000 mg/kg
Skin irritation	Rabbit	Non irritating
Eye irritation	Rabbit	Slight to Moderately irritating
Skin sensitisation	Guinea pig	Non sensitising

9.1.1 Oral Toxicity (Safepharm Laboratories Limited 1999d)

Test substance:	Notified chemical
Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	3/sex
Observation period:	14 days
Method of administration:	2 000 mg/kg by gavage
Test method:	OECD TG 401; EC Method B1 tris. Acute toxic class method - (EC 1996)
Mortality:	Nil
Clinical observations:	There were no clinical signs of systemic toxicity.
Morphological findings:	No abnormalities were noted at necropsy.
Estimated LD_{50}:	> 2 000 mg/kg (according to EC schema - (EC 1996)
Result:	The notified chemical was of very low acute oral toxicity to the rat.

9.1.2 Dermal Toxicity (Safepharm Laboratories Limited 1999b)

Test substance:	Notified chemical
Species/strain:	Rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A single, 24-hour semi occluded dermal application to intact skin at a dose level of 2 000 mg/kg bw.
Test method:	OECD TG 402; EC Method B3.
Mortality:	Nil
Clinical observations:	No clinical signs of systemic toxicity were noted.
Dermal response:	No signs of dermal irritation were noted.
Morphological findings:	No abnormalities were noted at necropsy.
LD_{50}:	> 2 000 mg/kg bw

Result:	The notified chemical was of low dermal toxicity to the rat.

9.1.3 Skin Irritation (Safepharm Laboratories Limited 1999a)

Test substance:	Notified chemical
Species/strain:	Rabbit/New Zealand white
Number/sex of animals:	3 males
Observation period:	3 days
Method of administration:	A single 4 hour, semi occluded application to intact skin.
Test method:	OECD TG 404; EC Method B4.
Dermal response:	Light pink coloured staining was noted at all treated skin sites 1, 24, 48 hours after patch removal but did not affect evaluation of dermal reactions. No oedema, erythema or eschar formation was observed. All individual Draize scores were zero.
Result:	The notified chemical was non irritating to rabbit skin.

9.1.4 Eye Irritation (Safepharm Laboratories Limited 1999c)

Test substance:	Notified chemical
Species/strain:	Rabbit/New Zealand white
Number/sex of animals:	2 males; 1 female
Observation period:	7 days
Method of administration:	A single instillation of 0.1 mL into the conjunctival sac of the right eye in one animal. The two remaining animals were then treated similarly. The left eye served as the control.
Test method:	OECD TG 405; EC Method B5.

Draize[1] scores of unirrigated eyes:

	Time after instillation									
Animal	***1 hour***		***24 hours***		***48 hours***		***72 hours***		***7 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1	0^S	0	0^S	0	0^S	0	0^S	0	0	0
2	0^S	0	0^S	0	0^S	0	0^S	0	0	0
3	0^S	0	0^S	0	0^S	0	0^S	0	0	0
Iris	*All individual scores were zero.* S *for all observation times for all animals, except on Day 7.*									
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	2	3^{Sf}	1	1	0^{Sf}	0	0	0^{Sf}	0	0	0^{Sf}	0	0	0^{Sf}
2	2^S	2	2^{Sf}	1	1	0^{Sf}	0	0	0^{Sf}	0	0	0^{Sf}	0	0	0^{Sf}
3	1^S	1	2^{Sf}	1	1	1^{Sf}	0	0	0^{Sf}	0	0	0^{Sf}	0	0	0^{Sf}

o = opacity, a = area, r = redness, c = chemosis, d = discharge.
S - purple-coloured staining; Sf - purple-coloured staining of fur around eye.

Individual mean scores at 24, 48 & 72 hours:
Corneal opacity: 0, 0, 0;
Iridial Inflammation: 0, 0, 0;
Conjunctival Redness: 0.3, 0.3, 0.3;
Conjunctival Chemosis: 0.3, 0.3, 0.3.

Ocular response:
Purple coloured staining of the cornea, iris and conjunctivae was present at the 72-hour observation time but did not interfere with the evaluation of ocular responses. No corneal or iridial effects were noted. Moderate conjunctival irritation was noted in all treated eyes one hour after treatment with minimal conjunctival irritation noted 72-hours after treatment.

Result:
The notified chemical was slight to moderately irritating to rabbit eye.

[1] See Attachment 1 for Draize scales.

9.1.5 Skin Sensitisation (Safepharm Laboratories Limited 1999k)

Test substance:	Notified chemical
Species/strain:	Guineapig/Dunkin Hartley White
Number of animals:	10 test and 5 control animals
Test method:	OECD TG 406 Magnusson and Kligman Maximisation Method; EC Method B6.
Induction procedure:	Intradermal Induction Test animals: Day 1: three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region: - Freund's Complete Adjuvant (FCA) in distilled water (1:1); - the test substance at 1% w/v in distilled water; - the test substance at 1% w/v in a (1:1) mixture of FCA and distilled water; Topical Induction: Day 7 – A 48-hour semi occluded application of filter paper loaded with 50% w/v of test substance in distilled water to the treated area; Control Animals: Treated similarly to the test animals omitting the test substance from the intradermal injections and topical application.
Challenge procedure:	Test and Control animals: Day 21: A 24 hour, semi occluded application of 50% w/v and 25% w/v of test substance in distilled water, to the left and right flank of each animal, respectively.

Challenge Outcome Dermal Responses:

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours****	***48 hours****
50%				
Grade 1 erythema	**5/10	5/10	1/5	0/5
Grade 1 oedema	5/10	5/10	1/5	0/5
Desquamation	0/10	6/10	0/5	2/5
25%				
Grade 1 erythema	0/10	0/10	1/5	0/5
Grade 1 oedema	0/10	0/10	1/5	0/5
Desquamation	1/10	1/10	0/5	0/5

* Time after patch removal. ** Number of animals exhibiting dermal responses.
Grade 1 erythema - discrete or patchy erythema. Grade 1 oedema - very slight oedema.

Challenge Outcome Comment: –	Purple-coloured staining was noted at the challenge sites of all test and control group animals but was stated not to interfere with evaluation of skin responses. The test substance was determined not to be sensitising on the basis that the severity of the dermal response for test animals was not more severe than that observed in control animals.
Result:	The notified chemical was non-sensitising to guineapig skin.

9.2 Repeated Dose Toxicity (Hita Research Laboratories 1999)

Test substance:	Analogue (free acid)
Species/strain:	Rat/Crj:CD(SD)IGS
Number/sex of animals:	6/sex/group
Method of administration:	Gavage
Dose/Study duration:	Treatment phase: 0, 40, 200 or 1 000 mg/kg/day for 28 consecutive days. Recovery phase: a treatment free period of 14 days. Recovery groups were separately provided for animals of the control and 1 000 mg/kg/day test groups.
Test method:	MITI (MITI 1986); EC Method B7 (EC 1996)

Clinical observations
There were no deaths during the treatment or recovery phase. Salivation was observed in one male at 200 mg/kg/day on Day 17 just after dosing, and in 11 animals at 1 000 mg/kg/day sporadically or continuously just after dosing from Day 3 to Day 28. Reddish stools observed in all test animals during the treatment phase had disappeared by the end of the recovery phase. Food consumption, bodyweight gain and findings from the functional observation battery were unremarkable.

Clinical chemistry/Haematology/Urinalysis
Decreased potassium levels were noted in males at 40 and 200 mg/kg/day. Decreased cholesterol levels were noted in recovery females at 1 000 mg/kg/day. Pink to red brown urine observed in animals at 200 and 1 000 mg/kg/day had disappeared at the end of the recovery phase.

Necropsy
Organ weights were unremarkable. Reddish change of the wall, and reddish contents in the stomach, duodenum, jejunum, ileum, caecum, colon and rectum observed during treatment were not observed in animals of the recovery phase.

Histopathology
At the end of treatment, pigment deposition was noted in the jejunum and ileum of animals at 1 000 mg/kg/day. Cyst formation and dilatation of tubules with fibrosis in the kidney was observed in one male at 1 000 mg/kg/day. Cyst formation in the kidney was noted in one female at 1 000 mg/kg/day and in one control female. At the end of the recovery phase basophilic tubules were observed in one male each of the control and 1 000 mg/kg/day groups.

Comment
No adverse effects related to treatment were observed in this 28-day study. Lesions of the kidney were considered to be incidental and not related to treatment. Reddish discolouration of gastrointestinal tract and contents was assumed to be due to the pigment containing chemical.

Result
The no observed adverse effect level (NOAEL) determined for the analogue substance is 1 000 mg/kg/day, the highest dose tested.

9.3 Genotoxicity

9.3.1 Bacterial Reverse Mutation Assay (BML 1999b)

Test substance:	Analogue (sodium salt)
Strains:	*Salmonella typhimurium*: TA100, TA1535, TA98, TA1537; *Escherichia coli*: WP2uvrA.
Auxillary Metabolic activation system:	Liver S9 fraction from rats induced with phenobarbital and 5,6 –benzoflavone
Concentration range:	0, 313, 625, 1 250, 2 500, 5 000 μg/plate
Test method:	OECD TG 471; MOL ((MOL 1997)); MITI ((MITI 1997b))
Comment:	No precipitation was noted; toxicity characterised by growth inhibition was not observed. There was no increase in the number of revertant colonies above the control, or demonstration of a dose response relationship, either in the presence or absence of metabolic activation at any test concentration.
Result:	The analogue was non mutagenic under the conditions of the test

9.3.2 Chromosomal Aberration Assay in Mammalian Cells (BML 1999a)

Test substance:	Analogue (sodium salt)
Cells:	Chinese hamster lung fibroblast cell line
Auxillary Metabolic activation system:	Liver S9 fraction from rats induced with phenobarbital and 5,6 –benzoflavone

Dosing schedule:	Each concentration was tested in duplicate, in two independent experiments as follows: Experiment 1: With and without metabolic activation, Treatment time = 6 hours; 0, 625*, 1 250*, 2 500*, 5 000* μg/mL; Experiment 2: Without metabolic activation, Treatment time = 24 hours 0, 313*, 625*, 1 250*, 2 500* μg/mL; Treatment time = 48 hours 0, 300*, 600*, 900*; 1 200* μg/mL. *cultures selected for metaphase analysis. Appropriate clastogenic control substances were used.
Test method:	OECD TG 473; MITI (MITI 1997a) MOL (MOL 1997)
Comment:	Cytotoxicity was not observed at any concentration. The test substance did not cause any significant increases in the incidence of cells with chromosomal aberrations, polyploidy or endoreplication, at the concentrations analysed in the presence or absence of metabolic activation; Positive controls used in the test caused marked increases in the incidence of aberrant cells and the activity of the S9 fraction was found to be satisfactory
Result:	The analogue was non clastogenic under the conditions of the test

9.4 Overall Assessment of Toxicological Data

The notified chemical is of very low acute oral toxicity and low dermal toxicity. It is non irritating to rabbit skin and did not elicit an allergic response when tested in guinea pigs using an adjuvant type technique. The notified chemical caused slight to moderate irritation to rabbit eye.

Investigations into repeat dose toxicity and genotoxicity were conducted on near identical chemical analogues, namely the free acid or sodium salt. It is considered that the notified chemical is not likely to be more toxic than the free acid or the sodium salt.

In a 28-day repeat oral dose study in rats, which incorporated a 14-day recovery phase, there was no mortality or adverse effects related to treatment for the free acid analogue. The NOAEL determined for this study is 1 000 mg/kg/day, the highest dose tested.

Mutagenicity was not observed in a bacterial study using the sodium salt analogue, nor was clastogenicity observed in a mammalian chromosome damage assay.

Based on the data supplied, the notified chemical would not be classified as a hazardous substance against the Approved Criteria for Classifying Hazardous Substances (NOHSC 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following studies have been conducted on the notified chemical unless otherwise stated. The tests were performed in compliance with OECD/EEC Test Methods and according to OECD Principles of GLP.

10.1 Summary of Ecotoxicity Data

Test	*Species*	*Test concentration (nominal) mg/L*	*Results (nominal) mg/L*
Fish Acute Toxicity (Semi-Static) (OECD TG 203)	Rainbow Trout *Oncorhynchus mykiss*	100	96 h LC_{50} > 100
Fish Acute Toxicity* (Semi-Static) (JISK)	Orange-red killifish *Oryzias latipes*	1 000	48 h LC_{50} > 1 000
Acute Toxicity – Immobilisation (Static Test) (OECD TG 202)	Water Flea *Daphnia magna*	100	48 h EC_{50} > 100 48 h NOEC = 100
Growth Inhibition (Static Test) (OECD TG 201)	Green Alga (*Scenedesumus subspicatus; strain CCAP 276/20*)	100	E_bC_{50} (72 h) > 100 E_rC_{50} (0-72 h) > 100 NOEC = 100
Respiration Inhibition (OECD TG 209)	Activated Sludge – Aerobic Waste Water Bacteria	1 000	3 h EC_{50} > 1 000 NOEC = 1 000

* Conducted on analogous substance.

10.2.1 Fish (Safepharm Laboratories Limited 1999e)

Rainbow trout (20 fish per group) were exposed for 96 hours to the test substance at 100 mg/L. The test substance was dissolved directly in water. The test was carried out in duplicate, under semi-static conditions. Analysis of the test preparations at 0, 24 and 96 hours showed the measured test concentrations to be near nominal. There was no mortality or sub lethal effects of exposure observed in either the control or test groups during the study. Based on nominal concentrations, the acute toxicity (LC_{50}) of the test substance to fish was determined to be greater than 100 mg/L. Based on the absence of mortality and sub-lethal effects at this concentration, the No Observed Effect Concentration (NOEC) is established at 100 mg/L.

10.2.2 Fish (Kurume Research Laboratories 1999a)

As part of the bioaccumulation test (Section 8), the acute toxicity of a near identical chemical to the notified chemical to orange-red killifish was determined. The fish (10 per group) were exposed for 48 hours to the test substance at 1 000 mg/L. The test substance was dissolved directly in water. The test was conducted under semi-static conditions. The acute toxicity (LC_{50}) of the analogous substance to fish was reported to be greater than 1 000 mg/L.

10.3 Aquatic Invertebrates (Safepharm Laboratories Limited 2000a)

Daphnids (10 animals per group) were exposed for 48 hours to the test substance at a single test concentration of 100 mg/L. The test substance was dissolved directly in water and the test conducted under static conditions. Four replicate test vessels were prepared with duplicate controls. Analysis of the test preparations at 0 and 48 hours showed the measured test concentrations to be near nominal. No immobilisation or adverse reactions to exposure were observed in either the control or test groups during the study. Based on nominal test concentrations, the acute toxicity (48 hour EC_{50}) of the test substance to daphnia was determined to be greater than 100 mg/L. Based on the absence of immobilisation at this concentration the NOEC is established at 100 mg/L.

10.4 Algal Inhibition Test (Safepharm Laboratories Limited 1999f)

Algae were exposed to the test substance at a single concentration of 100 mg/L for 72 hours under constant illumination. The test substance was dissolved directly in culture medium. Six replicate test flasks were prepared with triplicate controls. Analysis of the test preparations at 0 and 72 hours showed the measured test concentrations to be near nominal. No abnormalities were detected following microscopic inspection of all cultures. Neither growth (r) or biomass (b) of *Scenedesmus subspicatus* were affected by the presence of the test substance over the exposure period. Based on nominal test concentrations, growth inhibition (growth rate and biomass) is determined to be greater than 100 mg/L for both growth rate and biomass. There were no statistically significant differences between the control and test groups. Therefore, the NOEC is established at 100 mg/L.

10.5 Microorganisms (Safepharm Laboratories Limited 1999g)

Activated sewage sludge was exposed to the test material at a concentration of 1 000 mg/L for a period of 3 hours with the addition of a synthetic sewage as a respiratory substrate. The test substance was dissolved directly in water. Three replicate test flasks were prepared with duplicate controls. The reference material, 3,5-dichlorophenol was prepared at concentrations of 3.2, 10 and 32 mg/L; there were no replicates. Oxygen consumption rates were determined for test and reference flasks at 30 minutes and again at 3 hours contact time. 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 hour EC_{50} of greater than 1 000 mg/L. The NOEC was established at 1 000 mg/L.

10.6 Conclusion

Investigations into the acute ecotoxicity of the notified chemical on fish, daphnia and algae revealed no adverse effects, mortality or growth inhibition at the concentrations tested. On the basis of these findings, the notified chemical would be practically non-toxic to aquatic organisms (Zucker 1985). In the absence of data from chronic studies, no determination of long term effects can be made but none would be expected.

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

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will enter environmental compartments indirectly via disposal of waste paper (for recycling, to landfill or for incineration) and via direct release from discarded spent cartridges at landfill sites. On the basis of import volume, method of containment i.e. cartridge and low concentration in ink (5%), release of the notified chemical to the environment is expected to be minimal, but widespread.

Abiotic or slow biotic processes would be largely responsible for the degradation of the notified chemical as a near identical chemical was not shown to be readily biodegradable (1%). The octanol-water partition coefficient and ready water solubility indicate that the notified chemical will be predominantly distributed to water with soil absorption unlikely.

Any released chemical is not expected to be toxic to aquatic organisms as acute studies indicate very low toxicity. Although not specifically relevant to the mode of introduction and disposal identified in this notification statement, the notified chemical is not expected to adversely affect aerobic microbial treatment systems. In addition, the BCF calculated for a near identical substance indicates a low propensity for bioaccumulation (Mensink 1995). By analogy the notified chemical is expected to display the same low propensity. Further support for a low bioaccumulation potential of the notified chemical is the large molecular weight (>700) which would hinder passage through cell membranes and a very low octanol-water partition coefficient (log P_{ow} <-3.85) which indicates low fat solubility.

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

Assessment of Toxicological Hazard
Toxicology data assessed shows the notified chemical has low acute oral and dermal toxicity in rats. It is not a skin irritant in rabbit, but is a slight to moderate eye irritant in rabbits. The notified chemical was not a skin sensitiser in an adjuvant type study in guinea pigs.

A 28 day oral repeat dose toxicity was performed on the free acid form of the notified chemical. In the repeat dose (0, 40, 200 and 1000 mg/kg bw/day) toxicity study in rat, the NOAEL was 1000 mg/kg bw/day. Investigations into genotoxicity were conducted on the sodium salt of the notified chemical. In a bacterial reverse mutation assay the analogue was not mutagenic. In a chromosome aberration assay in a CHO lung fibroblast cell line the analogue was not considered clastogenic.

Based on the data supplied the notified chemical would not be classified as a hazardous substance against the Approved Criteria for Classifying Hazardous Substances (NOHSC 1999).

Occupational Health and Safety
The notified chemical will be imported in pre-packed sealed cartridges for colour printers, each containing 10 to 15 g of aqueous ink with a maximum of 5% notified chemical.

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, given the low concentration of the notified chemical in the ink cartridges and the anticipated low toxicity.

Exposure to the ink could be experienced by trained technicians during servicing of printers and by office or printing staff when a sealing tape is removed prior to inserting the ink cartridge into the printer, or attending to paper feed problems. Exposure would be by skin contact. Given the low hazard and low concentration, the notified chemical in the ink solution following contact is considered to be of low risk of adverse health effects.

Exposure may occur upon handling printed matter. However, the ink is heat fixed once applied to the printed surface, indicating the ink is not available for separate human exposure during the handling of printed materials.

Public Health
The notified chemical is intended for use by the public in colour printers. Whilst there may be some dermal exposure to the public through ink residues contained on/in printer surfaces, the toxicology profile indicates low hazard from skin contamination. Therefore, the potential risk of the notified chemical to the general public is considered low.

13. RECOMMENDATIONS

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

- Printer service technicians should receive regular instruction on good occupational hygiene practices in order to minimise personal contact, and contamination of the work environment with ink solutions containing the notified chemical.

- Personal protective equipment should be worn in activities where extensive exposure to the ink solution is likely to occur, for example, during spillage clean up or printer maintenance. Workers should be trained in the proper fit, correct use and maintenance of their protective gear. Guidance in the selection, personal fit and maintenance of personal protective equipment can be obtained from:

Safety glasses:	AS 1336 (SAA 1997)
	AS/NZS 1337 (SAA/SANZ 1992)
Impermeable gloves:	AS 2161.2 (SAA/SANZ 1998)
Protective clothing:	AS 2919 (SAA 1987)

- A copy of the MSDS for the notified chemical and the products that contain it should be easily accessible to employees.

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.

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

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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.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	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