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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

MCP-304

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

MCP-304

1. APPLICANT

Sharp Corporation of Australia Pty Ltd of No. 1 Huntingwood Drive, Huntingwood, Blacktown, NSW 2148 has submitted a standard notification for the assessment of MCP-304.

2. IDENTITY OF THE CHEMICAL

The chemical identity has been exempted from publication in the Full Public Report and the Summary Report as commercial interests may be prejudiced if disclosed.

Trade name: MCP-304

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: white powder

Melting Point: 188.5 -194.5°C (decomposes at 230°C)

Specific Gravity: 1.138 at 22°C

Vapour Pressure: 1×10^{-5} Pa at 25°C

Water Solubility: 3.4 g/L at 20°C

Partition Co-efficient (n-octanol/water) log P_{ow}: -0.176 at 20°C

Hydrolysis as a function of pH: 120 hours (5 days) at pH 4, 7 and 9 and 50°C, less than 10% hydrolysis occurs, equivalent to an environment half-life of greater than 1 year at all three pH values.

Adsorption/Desorption: due to the notified chemical's ionic nature, the cation and the anion were examined separately. The K_{oc} values are as follows:

Soil type	anion K_{oc}	cation K_{oc}
Sandy loam	7.3	288
Clay loam	1.1	~ 2000
Sandy silt loam	17.0	267

Dissociation Constant not provided

Flash Point: not conducted, MCP-304 is a solid

Flammability Limits: not flammable

Autoignition Temperature: not auto-flammable

Explosive Properties: not explosive

Reactivity/Stability: does not react with water and air

Particle size distribution: 18.0% by mass of MCP-304 is of particle size less than 10 μm

Comments on Physico-Chemical Properties:

The notified substance exhibits many properties that would lead to persistence and the ability to disperse in the soil and aquatic environment. Soil mobility except for the cation in clay soils is high. K_{oc} values of the anion shows a very high mobility in all three types of soil. K_{oc} values of the cation show MCP-304 as having a medium mobility in these soils.

4. PURITY OF THE CHEMICAL

Degree of purity : 99.8%

Toxic impurities: none

Non-toxic impurities: none

Additives/Adjuvants: none

5. INDUSTRIAL USE

The notified chemical is a charge control agent for toner and will be incorporated into a toner preparation to be used in photocopiers and other office machines.

The notified chemical will be imported to Australia at a rate of 0.1-1 tonnes per year for the first 3 years rising to 1-10 tonnes per year for the following 2 years.

6. OCCUPATIONAL EXPOSURE

A preparation which contains MCP-304 at not greater than 2% with the remainder mainly acrylic polymer resin and wax (together comprising 95% of toner) will be imported into Australia in 250 g plastic bottles.

To replenish toner in a photocopying machine the plastic top from a bottle is removed and the toner poured into a tray.

7. PUBLIC EXPOSURE

The majority of public exposure, which will be minimal, will result from dermal or eye contact, and inhalation of airborne particles, as the toner is being poured into the photocopiers or other office machines. In addition, the toner may be transferred from hands or fingers to the eyes. Minor public exposure may result from accidental spillage during transport and storage of the toner.

8. ENVIRONMENTAL EXPOSURE

. Release

As all formulation and packaging will be carried out overseas, no environmental exposure is expected in Australia from these processes.

Toner is added to photocopiers as required. The 250 g bottle containing the toner formulation is attached to the machine, and the empty toner container which may still hold up to 15% of the contents (0.6 g of the notified substance) is discarded. The product, its containers and materials contaminated with the chemical are recommended to be disposed of as domestic waste to landfill in accordance with local, State and Federal regulations.

Releases to the environment may occur through processing of waste paper. Using data supplied by the notifier, at the maximum projected import rate and allowing for 15% wastage in the photocopy machine, 64,000 tonnes of paper may potentially be presented for recycling. This possibility is explored further below.

. Fate

The chemical is likely to arrive in a dispersed manner in landfill bound to waste paper. As such, it may biodegrade slowly when placed in the landfill.

Paper recycling is a growing industry in Australia. Wastepaper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance fibre separation, ink detachment from the fibres, pulp brightness and whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat, washing, screening, cleaning, flotation and dispersion stages. The notifier has provided data on the likely behaviour of the chemical during the recycling process. The chemical will survive the above conditions, either remaining bound to the pulp or entering the aquatic compartment with a portion becoming associated with the sludge. In the latter case, the chemical may arrive in landfill, where it would be slow to biodegrade. However, given the soluble nature of the chemical, it is likely to remain in the aquatic compartment and be discharged with the waste water.

When subjected to a modified Sturm test (OECD No 301B), biodegradation at a concentration of 10 mg/L was 3% over a 28 day period, which means that the product is not readily biodegradable.

The notifier states in the submission that, "No chemical treatment is practicable to neutralise the hazardous environmental properties." This precludes the addition of some form of chemical treatment to the outlet waters to reduce hazard.

Bioaccumulation in aquatic organisms is not considered likely because of the low partition coefficient of the notified product.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of MCP-304

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 500 mg/kg	(1)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(2)
Acute inhalation toxicity	Rat	LC_{50} = 2.99 mg/L	(3)
Skin Irritation	Rabbit	non-irritant	(4)
Eye irritation	Rabbit	irritant	(5)
Skin sensitisation	Guinea-pig	non-sensitiser	(6)

9.1.1 Oral Toxicity (1)

LD_{50}: > 500 mg/kg *Species/strain:* Rat, CD strain

Number/sex of animals: 5M, 5F *Observation period:* 14 days

Method of administration (vehicle): gavage (0.5% w/v methylcellulose)

Clinical observations: salivation 1 hour after dosing at 500 mg/kg; no effects after 50 mg/kg

Mortality: One death at 500 mg/kg *Morphological findings:* no significant macroscopic abnormalities

Test Method: EEC Commission Directive 92/69/EEC (7)

9.1.2 Dermal Toxicity (2)

LD_{50}: > 2000 mg/kg *Species/strain:* Rat, strain CD

Number/sex of animals: 5 M, 5 F *Observation period:* 14 days

Method of administration (vehicle): occlusive dressing, 24 hour duration, applied as a fine, white powder to skin moistened with water

Clinical observations: no systemic or local sign of reaction to treatment

Mortality: no deaths *Morphological findings:* no significant macroscopic lesions

Test Method: EEC Commission Directive 92/69/EEC (7)

9.1.3 Inhalation Toxicity (3)

LD_{50}: 2.99 mg/L (male: 3.27 female: 2.89) *Species/strain:* Rat, strain CD

Number/sex of animals: 5 M, 5 F *Observation period:* 14 days

Method of administration: continuous, 4 hour, snout-only. Particle size average: 4.87μm; 53% < 6 μm

Clinical observations: Ante mortum signs comprised wet fur, reduced respiratory rate, exaggerated respiration and struggling for animals dying during exposure, together with underactivity, lethargy, prone position, staggering gait, slow and deep respiration, râles, gasping, muscle tremor, cold to touch, hunched posture, piloerection, ungroomed appearance, pigmented staining of the snout and pigmented orbital secretions for those dying after exposure. Signs in the surviving animals exposed to 2.28 or 3.64 mg/L were similar to the decedents and were fully resolved by day 4 or day 11 respectively. Signs in animals exposed to 1.33 mg/L were wet fur, reduced respiratory rate, exaggerated respiration and struggling during exposure, together with cold to touch, hunched posture, piloerection and underactivity after exposure. All animals were fully recovered on day 2.

Mortality: no deaths at 1.33 mg/L; 3 (M) and 1 (F) at 2.28 mg/L; 2 (M) 4 (F) at 3.64 mg/L *Morphological findings:* necropsy of the decedents revealed dark and/or incompletely collapsed lungs in 4 animals

Test Method: EEC Commission Directive 92/69/EEC (7)

9.1.4 Skin Irritation (4)

Result: non-irritant: no Draize (8) score above zero was recorded for any animal at 1 hour, 1, 2 or 3 days after decontamination

Species/strain: New Zealand White rabbits *Number/sex of animals:* 3 M

Method of administration: semi-occlusive dressing for 4 hours; 0.5 g of test material applied as a fine, white powder to skin moistened with water

Test Method: EEC Commission Directive 92/69/EEC (7)

9.1.5 Eye Irritation (5)

Result: irritant: at day 8 a bullous swelling of the cornea was evident, the surface of which was nacreous in appearance. In the light of this serious ocular effect in the single test animal, no further animals were used in the study

Species/strain: New Zealand White rabbit *Number of animals:* 1

Method of administration: 100 milligrams instilled into the conjunctival sac. The test material was a fine white powder

Test Method: EEC Commission Directive 92/69/EEC (7)

Draize (8) Scores[i]

Animal	Time after instillation														
	1 hour			1 day			2 days			3 days			8 days		
CORNEA:	opacity	area		opacity	area		opacity	area		opacity	area		opacity	area	
1	1	4		0	0		0	0		0	0		3	2	
IRIS															
1	1			1			0			0			0		
CONJUNCTIVA	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]	r[a]	c[b]	d[c]
1	2	2	3	3	1	3	2	0	1	2	0	1	1	0	0

[a] redness [b] chemosis [c] discharge

9.1.6 Skin Sensitisation (6)

Result: non-sensitiser

Species/strain: guinea-pig, Dunkin-Hartley *Number of animals:* 10 M, 10 F (test)
5 M, 5 F (control)

Induction: day 1: intradermal injections (0.1 mL) of FCA, 10% w/v MCP-304 in propylene glycol and 10% w/v MCP-304 in propylene glycol in FCA. Day 8: topical application of 30% w/v MCP-304 in propylene glycol covered by an occlusive dressing for 48 hours

Results:

Challenge* Concentration	24 hrs		48 hrs	
	test	control	test	control
5% w/v	0/20	0/10	0/20	0/10
30% w/v	0/20	0/10	0/20	0/10

* challenge on day 22, occluded application for 24 hours

Test Method: EEC Commission Directive 92/69/EEC (7)

9.2 Repeated Dose Toxicity (9)

Species/strain: Rat, CD *Number/sex:* 5 M, 5 F per dose

Method of administration (vehicle): gavage (0.5% w/v aqueous methylcellulose)

Dose/ Duration of administration: 0, 15, 150 or 500 mg/kg/day for 28 days

Toxicologically Significant Observations:

1. Clinical

No effect observed on bodyweight or bodyweight gain. Salivation throughout the study in animals treated at 150 or 500 mg/kg/day and on days 5 and 6 only in animals treated at 15 mg/kg/day

2. Clinical Chemistry/Haematology

No significant changes in haematology parameters. A number of minor reductions in alanine aminotransferase activity and in plasma urea, protein and creatinine concentrations at 500 mg/kg/day were not consistent across sexes. Slightly elevated plasma potassium concentrations in male rats.

At 150 mg/kg/day there were slight reductions in alanine aminotransferase.

3. Necropsy Findings/ Histopathology

Adrenal weights in females at 500 mg/kg/day were slightly elevated. No macroscopic or microscopic findings were noted.

4. Conclusion

No target organ was identified.

Test Method: EEC Commission Directive 92/69/EEC (7)

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (10)

Result: not mutagenic in presence or absence of metabolic activation (rat liver S9)

Strains: Salmonella typhimurium strains TA 98, TA 100, TA 1535 and TA 1537

Concentration range: 50 - 5000 μg/ plate

Test Method: EEC Commission Directive 92/69/EEC (7)

9.3.2 Chromosomal Aberrations in Cultured Human Peripheral Lymphocytes (11)

Result: non-clastogenic in the presence or absence of metabolic activation (rat liver S9). Slides for analysis selected on the basis of sufficient reduction in mitotic index.

Cell Culture/Exposure Time/Doses: 48 hour cultures from whole, human blood were exposed for 19 hours or 43 hours to doses of either 10 - 160 μg/mL (without S9) or 125 - 1000 μg/mL (with S9) MCP-304.

Test Method: EEC Commission Directive 92/69/EEC (7)

9.4 Overall Assessment of Toxicological Data

The notified chemical exhibited low acute oral and dermal toxicity but moderate inhalation toxicity in rats and no specific organ toxicity was observed in a 28-day repeated dose oral toxicity study at doses up to 500 mg/kg/day. It was not a skin irritant in rabbits but was a severe eye irritant. It was not a skin sensitiser in guinea-pigs and was not genotoxic as judged by induction of mutations in bacteria or chromosomal aberrations in cultured human peripheral lymphocytes.

On the basis of submitted data, the notified chemical would not be classsified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (12) in relation to Acute lethal effects (dermal) ; Irritant effects (skin), Sensitising effects (skin) or Severe effects after repeated or prolonged exposure (oral route). However, the notified chemical *would* be classified as harmful in relation to Acute lethal effects (inhalation) and severe eye effects but could not be classified in relation to Acute lethal effects (oral) although it would not be classified as toxic by the oral route.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Information submitted on ecotoxicology data, as required under the *Act* for this type of notification, has been summarised below.

Toxicological analyses were conducted in accordance with OECD and EC guidelines in all cases, using static conditions. All the results are based on measured concentrations taken during the test period.

Table 2 Summary of the ecotoxicity of MCP-304

Species	Time	Results
Rainbow trout	96 hr	EC_{50} >101 mg/L
		NOEC 10.8 mg/L
Daphnia magna	48 hr	EC_{50} 6.86 mg/L
		NOEC 1.23 mg/L
Selenastrum capricornutum	72 hr	E_rC_{50} >103 µg/L
		E_bC_{50} 71.1 µg/L

From these results it may be concluded that the substance is slightly toxic to fish moderately toxic to aquatic invertebrates but highly toxic to algae. This is as expected for quaternary ammonium salts (13).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The low environmental exposure of the chemical as a result of normal use indicates that the overall environmental hazard in use should be negligible.

Spillage during transport or disposal of spilt material in landfills should represent very minor risk to the environment, as the concentration of MCP-304 in the imported product is low.

Environmental exposure to the notified substance could occur when paper containing the chemical is recycled or disposed of. Exposure of the aquatic compartment to effluent resulting from paper recycling could potentially occur, due to the relatively high water solubility of the chemical and its resistance to biodegradation. The high toxicity to algae and the moderate toxicity of this chemical to fish and daphnia would thus be of concern.

The proportion of the total recycled paper that could contain the notified product is estimated at a maximum 6% of the total paper recycled each year (1,000,000 tonnes). There are several sites of recycled paper production in Australia which will act to disperse the chemical and reduce the environmental load. The very small proportion of this chemical in the formulated product and on the printed page (estimated by the company as 0.8 ng/page) should mean that this risk should be minimal, due to the expected high dilution that would result in very low final environmental concentrations.

There exists a potential for ecotoxicity to occur in the aquatic compartment if large volumes of paper containing the notified chemical are a significant proportion of the stock to be recycled at the one plant.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is expected to exhibit low toxicity by the oral and dermal routes. However, it would be expected to exhibit moderate toxicity by the inhalation route probably as a result of respiratory irritancy. There is a low probability of severe effects after repeated or prolonged exposure. It is not likely to be a skin irritant or a skin sensitiser and is not likely to exhibit genotoxicity. However, the notified chemical appears capable of producing irreversible eye damage.

Exposure to the notified chemical is expected to be low, principally because it is contained in toner for photocopy and other office machines at a level of less than 2%. Exposure to the toner is possible when pouring toner into trays contained in the machines and is expected to result from airborne contamination. However, this exposure is expected to be intermittent, as is exposure during machine cleaning or maintenance.

The risk of adverse occupational or public health effects occurring as a result of transport, storage, use or disposal of the notified chemical is expected to be low.
The main potential risk factor, viz., eye damage, is mitigated by the low level of MCP-304 in the toner - at 2% this level in below that which would result in the toner being classified as hazardous according to the criteria of Worksafe Australia (12).

13. RECOMMENDATIONS

If engineering controls and work practices are insufficient to reduce exposure to MCP-304 to a safe level, then:

the appropriate respiratory device should be selected and used in accordance to Australian Standard/ New Zealand Standard (AS/ NZS) 1715 and should confrom to AS/NZS 1716.

eye protection should be selected and fitted in accordance to AS 1336 and used in accordance to AS/NZS 1337.

(1) industrial clothing must conform to AS 2919 .
(2) industrial clothing providing general or specific protection from hazardous chemicals should conform to AS 3765.1
(3) industrial clothing providing limited specific protection from hazardous chemicals should conform to AS 3765.2.

(1) industrial gloves should conform to AS 2161.
(2) industrial gloves providing specific protection should conform to AS 3765.1.

particular care should be taken to avoid spillage of the notified chemical.

good personal hygiene should be practised to minimise the potential for ingestion.

a copy of the Material Safety Data Sheet should be easily accessible to employees.

If the concentration of MCP-304 exceeds 10% in a formulation then the Director should be advised in writting.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for MCP-304 was provided in Worksafe Australia format (14).

This MSDS was provided by Sharp Corporation of Australia Pty Ltd as part of their notification statement. The accuracy of this information remains the responsibility of Sharp Corporation of Australia Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of MCP-304 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. In addition, a secondary notification shall be required if more than 10 tonnes of the notified chemical are to be imported in which case an estimate of the likely concentration in the recycling effluent will be required.

16. REFERENCES

1. Pharmaco-LSR Ltd, 1994, *MCP-304: Acute Oral Toxicity Study in the Rat*, Report No. 93/1160, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

2. Pharmaco-LSR Ltd, 1994, *MCP-304: Acute Percutaneous Toxicity Study in the Rat*, Report No. 93/1214, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

3. Pharmaco-LSR Ltd, 1994, *MCP-304: Acute Inhalation Toxicity Study in the Rat*, Report No. 94/0684, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

4. Pharmaco-LSR Ltd, 1994, *MCP-304: Acute Dermal Irritation Test in the Rabbit*, Report No. 94/0034, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

5. Pharmaco-LSR Ltd, 1994, *MCP-304: Acute Eye Irritation Test in the Rabbit*, Report No. 94/0209, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

6. Pharmaco-LSR Ltd, 1994, *MCP-304: Delayed Contact Hypersensitivity Study in the Guinea-Pig*, Report No. 93/1176, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

7. EEC Commission Directive 92/69 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, *Official Journal of the European Communities* No. L 383 (29 December 1992)[1].

8. 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**.

9. National Occupational Health and Safety Commission, 1994, *Approved Criteria For Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australian Government Publishing Service, Canberra, Australia.

10. Pharmaco-LSR Ltd, 1994, *MCP-304: Four-week Oral Toxicity Study in the Rat*, Report No. 94/0205, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

11. Pharmaco-LSR Ltd, 1994, *MCP-304: Assessment of Mutagenic Potential in Histidine Auxotrophs of Salmonella typhimurium (the Ames Test)*, Report No.

[1] The tests specified in this directive relevant to the current notification are as follows:

- Test B1 Acute toxicity (oral)
- Test B2 Acute toxicity (inhalation)
- Test B3 Acute toxicity (dermal)
- Test B4 Acute toxicity (skin irritation)
- Test B5 Acute toxicity (eye irritation)
- Test B6 Skin sensitisation
- Test B7 Repeated dose (28 days) toxicity (oral)
- Test B10 Mutagenicity (*in vitro* mammalian cytogenetic test)
- Test B14 Mutagenicity (*Salmonella typhimurium* - reverse mutation assay)

94/0205, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

12. Pharmaco-LSR Ltd, 1994, *MCP-304: An in vitro Test for Induction of Chromosome Damage: Cytogenetic Study in Cultured Human Peripheral Lymphocytes*, Report No. 94/0254, data on file, Mitsubishi-Kasei Institute of Toxicological and Environmental Sciences, Tokyo, Japan.

13. Cooper J C., 1988, ' Review of the Environmentally Toxicity of Quaternary Ammonium Halides' , *Ecotoxicity and Environmental Safety*, **16,** 65-71.

14. National Occupational Health and Safety Commission, 1990. *, Guidance Note for the Completion of a Material Safety Data Sheet*, 2nd. edition, AGPS, Canberra , Australia.[2]

[i] The Draize scale for evaluation of eye reactions is as follows:

CORNEA			
Opacity rating	**rating**	**Area of Cornea involved**	
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 severe	3 severe	Swelling with lids half-closed	3 mod.	Disharge with moistening of lids and hairs and considerable area around eye	3
		Swelling with lids half-closed to completely closed	4 severe		

[2] This Guidance Note, to which an MSDS must conform in accordance with the *Act,* has been superseded by Worksafe Australia's National Code of Practice for the Preparation of Material Safety Data Sheets (March 1994) published by the Australian Government Publishing Service.

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