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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

ETHANAMINIUM, N,N-DIETHYL-N-METHYL-2-[(2-METHYL-1-OXO -2-PROPENYL)OXY]-, SALT WITH 4-METHYLBENZENESULFONIC ACID (1:1), POLYMER WITH BUTYL 2-PROPENOATE AND ETHENYLBENZENE

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989, as amended* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health, Housing, Local Government and Community Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

ETHANAMINIUM, N,N-DIETHYL-N-METHYL-2-[(2-METHYL-1-OXO-2-PROPENYL)OXY]-, SALT WITH 4-METHYLBENZENESULFONIC ACID (1:1), POLYMER WITH BUTYL 2-PROPENOATE AND ETHENYLBENZENE

1. APPLICANT

Mita Copiers Australia Pty Ltd, 25 Sirius Rd, Lane Cove, N.S.W.

2. IDENTITY OF THE CHEMICAL

Chemical name: Ethanaminium, N,N-diethyl-N-methyl-2-[(2-methyl-1-oxo-2-propenyl)oxy]-, salt with 4-methylbenzenesulfonic acid (1:1), polymer with butyl 2-propenoate and ethenylbenzene

Chemical Abstracts Service (CAS) Registry No.: 133350-42-2

Other name: Methacryloyloxyethyl, N,N-diethyl-N-methyl-ammonium-4-methylbenzenesulfonate, polymer with butyl acrylate and styrene

Trade names: Seigyozai J, Acrybase FCA-201-PZ

Molecular formula: $[(C_8H_8)_a.(C_7H_{12}O_2)_b.(C_{18}H_{29}O_5NS)_c]_n$

Structural formula:

Number-average molecular weight: 5110

Maximum percentage of low molecular weight species (molecular weight < 1000): 0.24%

Monomers:

. **Chemical name:** Ethenylbenzene
Synonym: Styrene
CAS No.: 100-42-5
Weight percentage: 71.3%

. **Chemical name:** Butyl 2-propenoate
Synonym: Acrylic acid, butyl ester
CAS No.: 141-32-2
Weight percentage: 13.9%

Chemical name: 2-Propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester
Synonym: 2-(Diethylamino)ethyl methacrylate
CAS No.: 105-16-8
Weight percentage: 7.4%

Chemical name: Benzenesulfonic acid, 4-methyl-, methyl ester
Synonyms: p-Toluenesulfonic acid, methyl ester
4-Methylbenzenesulfonic acid, methyl ester
CAS No.: 80-48-8
Weight percentage: 7.4%

Method of detection and determination:

IR spectroscopy

Spectral data:

The IR spectrum displays major characteristic peaks at 699.8, 759.8, 1197.5, 1492.9, 1600.7, and 1730.9 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Yellowish powder

Glass-transition Temperature: 70°C

Density: 1100 kg/m^3

Water Solubility: Insoluble

Decomposition Temperature: >300°C

Reactivity/Stability: Stable under ambient conditions; hazardous polymerisation will not occur

Particle size distribution: 92% > 150µm

Comments on physico-chemical properties:

The presence of carboxylic acid ester groups in the polymer indicates a potential for hydrolysis to products with increased water solubility. The polymer is described as insoluble, but without an analytical detection limit. Therefore, the possibility that this polymer, in view of its cationic nature, may have a measurable solubility, can not be excluded. The lack of test results is acceptable for the proposed level of importation.

4. PURITY OF THE CHEMICAL

Degree of purity (of the notified chemical alone): >99.5%

Toxic or hazardous impurity/impurities:

. **Chemical name:** Ethenylbenzene
Synonyms: Styrene
CAS No.: 100-42-5
Weight percentage: <0.5%
Toxic properties: 213 mg/m^3 (TWA), Worksafe Exposure standard (1). Mildly toxic to humans by inhalation. A suspected human carcinogen. An experimental carcinogen and teratogen. Skin and eye irritant (2).

Maximum content of residual monomers: 0.5%

5. INDUSTRIAL USE

The notified chemical is to be imported as an ingredient (charge control agent) of dry toner for commercial fax machines at a rate of less than 1 tonne annually for the first 5 years. The toner contains 2% of the notified chemical.

6. OCCUPATIONAL EXPOSURE

The notified chemical is to be imported in a sealed developing unit containing the toner.

It is estimated that operators of fax machines may be exposed to the toner during operation at a level of about 0.02 mg/m^3.

During exchange of the toner cartridge, some spillage of the toner is possible but is expected to be minimal.

Exposure to spilled toner may occur during maintenance of fax machines but this is expected to be minimal.

7. PUBLIC EXPOSURE

Potential public exposure to the notified chemical will occur during the use of the commercial fax machine, where it is estimated that the actual toner dust concentration in the air will be less than 0.02 mg/m^3. As the notified chemical comprises only 2% of the toner, actual exposure to the notified chemical through dust particles in the air is expected to be minimal.

Exposure to the notified chemical may occur during the maintenance of the fax machine, arising from accidental spillages and in the clean up process. As this is performed infrequently, public exposure is expected to be minimal.

8. ENVIRONMENTAL EXPOSURE

. Release

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

Similarly, no spillage during use is anticipated, as the polymer will be used in sealed cartridges. The material safety data sheets contain instructions to sweep up any spillages and dispose of them by incineration or contract with a licensed waste disposal company. The toner cartridge will be incinerated at a permitted facility in accordance with local, State or Federal regulations.

Releases to the environment may occur through processing of waste paper. This possibility is explored further below.

. Fate

Unless incinerated, the polymer is likely to arrive in a dispersed manner to landfill bound to waste paper. As such, it will be immobile, and no leaching from landfill would be expected despite the polymer's expected persistence.

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 no data on the likely behaviour of the polymer during the recycling process. The presence of carboxylic acid ester groups in polymers indicate a potential for hydrolysis to products with increased water solubility. The polymer is likely to survive the above conditions, either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the polymer will either arrive in landfill where it can be expected to remain intact, or be destroyed through incineration.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicity tests are not required for polymers of NAMW > 1000. However, some studies have been undertaken and the data are presented here.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Acrybase FCA-201-PZ

Test	Species	Outcome	Reference
Acute Oral Toxicity	Rat	>5.0 g/kg	3
Skin Irritation	Rabbit	non-irritant	4
Eye Irritation	Rabbit	non-irritant	5

9.1.1 Oral Toxicity (Ref No:3)

The notified chemical in 50% corn oil was administered via a single dose to five male and five female CD rats by gavage at 5.0 g/kg body weight. After 15 days the animals were killed and examined macroscopically.

No deaths occurred during the 15 day observation period. Pilo-erection was observed throughout the first day but no other clinical signs were noted. No macroscopic abnormalities were observed for animals killed on day 15.

The acute oral LD_{50} of the notified chemical was >5.0 g/kg.

9.1.4 Skin Irritation (Ref No:4)

Five hundred milligrams of the notified chemical was applied under a moistened 2.5 cm X 2.5 cm gauze pad to the dorsal region of each of 3 New Zealand white rabbits. The hair was removed from each site with electric clippers 24 hours prior to application of the pad. Each treatment site with the gauze applied was then covered with an elastic adhesive dressing for a 4 hour period. At the end of the exposure period, the semi-occlusive dressing and gauze pad were removed and the treatment site was washed with warm water to remove any residual test substance and blotted dry with absorbent paper.

No erythema or oedema was observed in any animal and no clinical signs were noted during a 4 day post-treatment observation period.

9.1.5 Eye Irritation (Ref No:5)

Approximately 60 mg of the notified chemical was placed into the everted lower lid of one eye of each of 3 New Zealand white rabbits. The eyelids of each treated eye were gently held together for one second after instillation. The contralateral eye remained untreated.

Observations were made at 1 hour and 1, 2, 3, 4 and 7 days following treatment. Mild conjunctival redness was noted in all animals at 1 hour and in 1 animal at 1 day post-treatment. No effects on the cornea, iris or conjunctiva of any animal at any other time point were noted.

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (6)

The notified chemical was tested for the induction of prototrophic back mutants in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 and *Escherichia coli* strain WP2 *uvrA* in the presence and absence of metabolic activation (rat liver S9). The solvent used was dimethylsulphoxide and appropriate positive and negative controls were included. The notified chemical, positive control substances, bacteria and S9 mix were incorporated into the agar overlay prior to plating.

The positive and negative controls gave the expected responses. No toxicity was observed at any dose level and no significant increase in the number of mutant colonies over the negative controls was observed in any strain at any dose level with or without S9. Doses of Acrybase FCA-201-PZ were 0, 312.5, 625, 1250, 2500 and 5000 µg per plate.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity, was not a skin irritant, not an eye irritant and was not genotoxic as measured by induction of mutations in bacteria.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1000 according to the *Industrial Chemicals (Notification and Assessment) Act, 1989, as amended*.

Normally, the notified substance would not be expected to exhibit toxic characteristics because large insoluble polymers of this nature are not readily absorbed by biota. However, the cationic nature of the polymer may confer some fish toxicity (7), although exposure of the aquatic compartment should be low.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The low environmental exposure of the polymer as a result of normal use indicates that the overall environmental hazard should be minimal.

Environmental exposure to the notified substance could occur when paper containing the polymer is recycled or disposed of. In each case, the final destination is likely to be landfill where the polymer can be expected to persist but remain immobile, being either bound to paper or to the sludge from the recycling process.

Accidental spillage of the polymer should result in a minimal hazard as it will be marketed in small packages for direct insertion into fax machines.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological profile of the notified chemical suggests it is of low acute oral toxicity, is not a skin or eye irritant and is not genotoxic. Particles of the notified chemical are not respirable, and therefore, the potential for entry of the notified chemical into the lungs is low. Due to the high molecular weight of the polymer, it is not expected to cross biological membranes following dermal exposure. As both the public and occupational exposures to the notified chemical are expected to be minimal and its intrinsic hazard is low, the risks associated with the use of the chemical are expected to be minimal.

13. RECOMMENDATIONS

To minimise occupational and public exposure to Acrybase FCA-201-PZ the following guidelines and precautions should be observed:

. the workplace should be well ventilated;

. good work practices should be implemented to avoid spillages;

. good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal in accordance with local or State regulations;

. good personal hygiene should be observed; and

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

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Acrybase FCA-201-PZ (Attachment 1) and the fax machine toner containing the notified chemical (Attachment 2) were provided in Worksafe Australia format (Ref No:8). These MSDS were provided by Mita Copiers Australia as part of their notification statement. They are reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Mita Copiers Australia.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989, as amended* (the Act), secondary notification of Acrybase FCA-201-PZ shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Also, for an import volume in excess of 1 tonne per year, additional environmental information will be required. This would need to include test results, literature support or argument for water solubility, hydrolytic stability (including under paper recycling) and data on aquatic toxicity.

16. REFERENCES

1. National Occupational Health and Safety Commission, Exposure Standards for Atmospheric Contaminants in the Occupational Environment, Australian Government Publishing Service Publ., Canberra, 1991.

2. Dangerous Properties of Industrial Materials, 7th Ed., Sax N. I. and Lewis R. J. Sr Eds, Van Nostrand Reinhold, 1989.

3. Huntingdon Research Centre Ltd, Cambridgeshire, England, Acrybase FCA-201-PZ Acute Oral Toxicity to the Rat, Project No.: 91749D/FJK 14/AC 1992.

4. Huntingdon Research Centre Ltd, Cambridgeshire, England, Acrybase FCA-201-PZ Skin Irritation to the Rabbit, Project No.: 91778D/FJK 15/SE 1991.

5 Huntingdon Research Centre Ltd, Cambridgeshire, England, Acrybase FCA-201-PZ Eye Irritation to the Rabbit, Project No.: 91790D/FJK 16/SE 1992.

6. Huntingdon Research Centre Ltd, Cambridgeshire, England, Acrybase FCA-201-PZ Bacterial Mutation Assay, Project No.: FJK 17B/911252, 1992.

7. EPA Proposed Revisions to Expand Criteria for Exempting Polymers from Premanufacture Notification, Chemical Regulation Reporter, pp. 2226-2247, 1993.

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