File No: NA/435

Date: November 1996

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Acrybase FCA-181P

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Acrybase FCA-181P

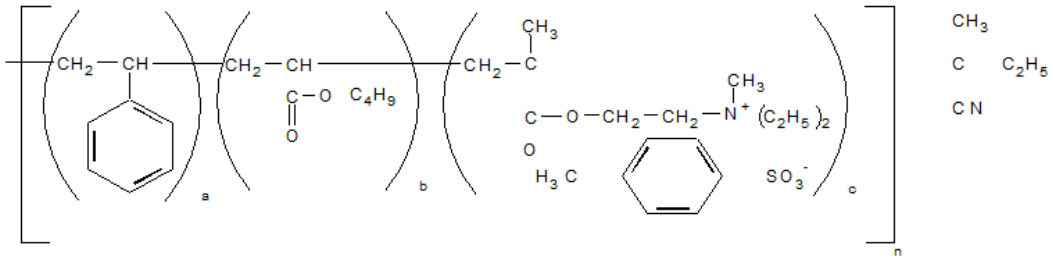
1. APPLICANT

Kyocera Electronics Australia Pty Ltd of Unit 8, 43-45 Herbert Street ARTARMON NSW 2064 has submitted a limited notification statement in support of their application for an assessment certificate for Acrybase FCA-181P.

2. IDENTITY OF THE CHEMICAL

Chemical name:	2-propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester, polymer with butyl 2-propenoate and ethenylbenzene, 2,2'-azobis[2-methylbutanenitrile] -initiated, compd with methyl *p*-toluenesulfonate
Chemical Abstracts Service (CAS) Registry No.:	141091-64-7
Other names:	2-propenoic acid, 2-methyl-, 2-(diethylamino)ethyl ester, polymer with butyl 2-propenoate and ethenylbenzene, compd with methylbenzenesulfonate, 2,2'-azobis[2-methylbutanenitrile]-initiated 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-propanoate and ethenylbenzene
Trade name:	Acrybase FCA-181P
Molecular formula:	$[(C_8H_8)_a - (C_7H_{12}O_2)_b - (C_{18}H_{29}O_5NS)_c]_n - C_5H_8N$

Structural formula:



Number-Average Molecular Weight: 5 100

Weight-Average Molecular Weight: 6 350

Maximum percentage of Low Molecular Weight Species Molecular Weight < 1 000: 0.24%

Weight percentage of ingredients:

Chemical Name	*CAS No.*	*Weight %*
ethenylbenzene	100-42-5	66.7
butyl-2-propenoic acid	141-32-2	18.0
2-methyl-2-(diethylamino)ethyl-2-propenoic acid	105-16-8	5.4
4-methyl-benzenesulfonic acid methyl ester	80-48-8	5.4
2,2-azobis(2-methyl-butanenitrile)	13472-08-7	4.5

Method of detection and determination: gel permeation chromatography (GPC), infrared spectroscopy

Spectral data: infrared; major characteristic peaks were found at: 699.8, 759.8, 1 197.5, 1 371.9, 1 452.2, 1 492.9, 1 600.7, 1 730.9, 2 926.5, 3 025.5, 3 059.1 cm^{-1}

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: yellowish powder

Glass transition: 60°C (at 760 mm Hg)

Specific gravity: 1.1

Vapour pressure:	not applicable - notified polymer is a solid
Water solubility:	0.031 g/L at 20°C
Partition co-efficient (n-octanol/water):	not determined
Hydrolysis as a function of pH:	not determined
Adsorption/desorption:	not determined
Dissociation constant:	not determined

Particle size:

> 700 μm	31.5%
350 μm - 700 μm	45.7%
250 μm - 350 μm	19.6%
< 250 μm	3.2%

Flash point:	not determined
Flammability limits:	not determined
Autoignition temperature:	not determined
Explosive properties:	not determined
Reactivity/stability:	notified chemical is stable under ambient conditions; hazardous polymerisation will not occur

Comments on Physico-Chemical Properties

Water solubility was determined by a gravimetric evaluation method. This involves the sample being dissolved in distilled water and shaken for 24 hours. The insoluble material is then isolated from the sample solution using filter paper. This test is not suitable for determining true water solubility as it determines the solution/extraction behaviour of the polymer (determined to be 0.031 g/L) similar to the draft OECD Test Guideline, and the figure may represent low molecular weight species solubilities. The polymer contains a low amount of quaternary ammonium salt functionalities that could confer some solubility. However, the test indicates that this is minimal.

Hydrolysis, partition coefficient, adsorption/desorption and dissociation constant have not been determined due to the low solubility of the polymer. This is acceptable

as hydrolysis of the ester linkages of the polymer would not be expected under environmental conditions.

Given the expected low solubility in water it is anticipated that the partition coefficient

for the polymer would be high. On the basis of the polymer's low water solubility it is likely to adsorb to, or be associated with soil/sediment and organic matter and be immobile in soil.

4. PURITY OF THE CHEMICAL

Degree of purity: > 99.5%

Toxic or hazardous impurities:

Chemical name:	styrene monomer
CAS No.:	100-42-5
Weight percentage:	< 0.1%
Toxic properties:	harmful by inhalation, irritating to eyes and skin; suspected human carcinogen (1, 2)

Non-hazardous impurities (> 1% by weight): none

Maximum content of residual monomers: 0.2%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

Acrybase FCA-181P will not be manufactured or reformulated in Australia. The polymer will be used as a charge control agent for dry toner in printers and will be imported at a concentration of less than 2% in toner products. The estimated import volume of Acrybase FCA-181P is less than 1 000 kg per year for the first 5 years.

6. OCCUPATIONAL EXPOSURE

Dry toner containing the notified chemical will be imported in individual plastic cartridges which will fit directly into office printers. The cartridges will contain a maximum of 800 g of toner (no more than 16 g notified chemical). Cartridges will be individually packaged in cardboard boxes for transport.

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical under normal circumstances.

Office workers may be minimally exposed to the notified chemical during the operation and maintenance of printers which use toner containing the notified

chemical. Cartridges are designed to limit exposure to toner products, however, dermal exposure may occur if toner containing the notified chemical is spilled while changing printer cartridges. Inhalational exposure to the notified chemical is expected to be low, as the notified chemical makes up less than 2% of the final toner product. In addition, the notifier claims that the level of toner dust in the vicinity of operating printers is around 0.02 mg/m^3, and less than 3.2% of the toner particles fall into the size range considered inspirable by the American Conference of Governmental Industrial Hygienists (cited in (3)). Contact with paper printed with the toners containing the notified chemical is unlikely to result in dermal exposure, as the notified chemical will be fixed to the paper as part of the toner product.

Printer repair personnel have the potential to come into contact with the notified chemical more often than office workers, although exposures are still expected to be minimal, due to the design of the toner cartridges.

7. PUBLIC EXPOSURE

There is little potential for public exposure to Acrybase FCA-181P arising from the import of the toner cartridges.

The notifier does not plan to manufacture the notified chemical in Australia and hence there are no wastes or emission arising from production facilities. The toner cartridges are installed inside printers and the overall design limits user access or exposure to the toner even when changing cartridges.

During printing the toner is transferred to paper and is firmly adherent. Most of the notified substance will enter the public domain in this form. Casual contact with the ink fixed on paper is unlikely to lead to even minor dermal exposure to the notified chemical.

8. ENVIRONMENTAL EXPOSURE

Release

The notified polymer is a component of a toner that is contained within a cartridge (800 g). It is expected that when the printer indicates that it requires more toner, the operator removes the spent cartridge and replaces it with a new one. Therefore, release of the notified polymer under normal conditions of use is expected to be negligible, as practically no waste is generated. Residues of the toner remaining in the cartridge are estimated at a maximum of 5%, which represents 50 kg of the notified polymer per year.

Releases to the environment as a result of accidents (during transport or in the workplace) are expected to be negligible.

The spent toner cartridge and any spills of toner will be disposed of as domestic waste, in accordance with government regulations (eg landfill, incineration). The

spent toner cartridge may also be sent back to the manufacturer for re-use.

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

Fate

Disposal of the notified polymer to landfill is unlikely to result in contamination of surface and ground waters. Its low water solubility, high molecular weight and large molecular size indicate it is unlikely to leach.

Combustion of the notified polymer in the presence of excess air will result in products of oxides of carbon, nitrogen and sulphur, and water.

Unless incinerated, the polymer is likely to arrive in a dispersed manner in 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.

Bioaccumulation of the polymer is not expected due to the very large molecular size that is likely to inhibit membrane permeability and prevent uptake during exposure (4).

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 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 or be destroyed through incineration.

9. EVALUATION OF TOXICOLOGICAL DATA

According to the Act, toxicological data are not required for polymers with a number-average molecular weight (NAMW) > 1 000, although the data summarised below were submitted by the notifier.

9.1 Acute Toxicity

Summary of the acute toxicity of Acrybase FCA-181P

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(5)
skin irritation	rabbit	non-irritating	(6)
eye irritation	rabbit	mild irritant	(7)

9.1.1 Oral Toxicity (5)

Species/strain:	rat; Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	gavage; 5 000 mg/kg test substance administered at a concentration of 50% (w/v) in aqueous methylcellulose
Clinical observations:	none
Mortality:	none
Morphological findings:	none
Test method:	according to OECD guidelines (8)
LD_{50}:	> 5 000 mg/kg
Result:	low oral toxicity in rats in a limit test with a single dose of 5 000 mg/kg

9.1.2 Skin Irritation (6)

Species/strain:	rabbit; albino
Number/sex of animals:	3; male
Observation period:	4 days
Method of administration:	0.5 g of test substance was applied under a 2.5 cm^2 gauze pad moistened with 0.5 mL water to one intact skin site on each animal; treatment site occluded with adhesive dressing for 4 h; dressing removed and site

	washed with water; observations made at 30 min, 2, 3 and 4 days after removal of dressing and scored according to the method of Draize (9)
Test method:	according to OECD guidelines (8)
Result:	there were no Draize scores greater than 0; the test substance was found to be non-irritating to intact rabbit skin

9.1.5 Eye Irritation (7)

Species/strain:	rabbit; albino
Number/sex of animals:	3; female
Observation period:	7 days
Method of administration:	approximately 50 mg (0.1 mL) test material placed on lower everted lid of one eye; untreated eye served as control; observations were made at one hour, 1, 2, 3, 4 and 7 days after installation and scored according to the method of Draize (9)
Comments:	one animal had slight conjunctival redness (Draize score of 1) at day 1 and 2 readings; the eye had returned to normal by day 3
Test method:	according to OECD guidelines (8)
Result:	test material is a mild eye irritant in rabbits

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (10)

Strains:	TA 1535, TA 1537, TA 1538, TA 98 and TA 100; *E. coli* WP2 *uvrA*
Concentration range:	312 - 5 000 μg/plate
Test method:	according to OECD guidelines (8)

Result:	not mutagenic in the bacterial strains tested in the presence or absence of metabolic activation provided by rat liver S9 fraction

9.4 Overall Assessment of Toxicological Data

According to the Act, toxicology data are not required for polymers with a NAMW > 1 000, however some data were submitted as part of the notification package. The notified polymer exhibited low acute oral toxicity in rats (LD_{50} > 5 000 mg/kg), was non-irritating to rabbit skin and a mild eye irritant when tested in rabbits. No bacterial mutagenicity was observed when the notified polymer was tested with or without metabolic activation.

The notified chemical is insoluble in water and is not expected to decompose under normal conditions of use. The NAMW exceeds 5 110 daltons and hence the chemical is not expected to cross biological membranes. The level of low molecular weight species (MW < 1 000; 0.24%) is not expected to cause adverse health effects.

Based on this information, the notified chemical would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1 000 according to the Act.

Water soluble cationic polymers with NAMW > 1 000, including quaternary amines, have the potential to be of some concern in aquatic toxicity. However, these effects are highly mitigated by the presence of dissolved organic carbon found in natural waters (12). In this case exposure of the aquatic compartment is also expected to 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 negligible.

Environmental exposure to the notified substance could occur when paper containing the polymer is disposed of or recycled. 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.

Exposure to aquatic environments is expected to be low thus the environmental

hazard should be negligible.

Accidental spillage of the polymer should result in negligible hazard as it will be marketed in cartridges for direct insertion into printers.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Waterside, warehouse and transport workers will be only be exposed to the notified chemical in the event of an accident or damage to packaging. The occupational health risk to these workers is negligible, particularly considering the low concentration of the notified chemical in toner products.

Office workers are not expected to come into contact with the notified chemical under normal circumstances. The design of the toner cartridges is such that exposure to Acrybase FCA-181P should be minimal, even when changing toner cartridges. Minor dermal exposure may occur if a small quantity of toner is spilt while changing cartridges. If eye contact occurs, the notified chemical or other toner components may cause mild eye irritation. There may be a low level of toner dust in the immediate vicinity of printers when they are operating, although inhalational exposure to the notified chemical (which is at a concentration of < 2% within toners) is expected to be negligible. Exposure to the notified chemical is not expected to occur once the toner is bound to paper. Based on the low toxicity and low irritancy of the chemical and the expected very low exposures, the health risk posed to office workers is negligible.

Likewise, a low occupational health risk exists for repair workers, who may be dermally or inhalationally exposed to low concentrations of the notified chemical (possibly more frequently than office workers) when repairing printers.

There is negligible potential for public exposure to Acrybase FCA-181P during the importation and distribution of toner products. There may be widespread public contact with the notified substance on the surface of printed paper, but its adhesion to the substrate and physico-chemical properties preclude absorption across the skin or other biological membranes.

13. RECOMMENDATIONS

To minimise occupational exposure to Acrybase FCA-181P the following guidelines and precautions should be observed:

- Work areas around printers should be well ventilated and good work practices should be implemented to avoid the generation of dusts;

- Spillage of toner products should be avoided and good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the Material Safety Data Sheet (MSDS) and/or information about the Kyocera toners containing Acrybase FCA-181P should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (13).

This MSDS was provided by the applicant as part of the notification statement. 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 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Secondary notification, including information on aquatic toxicology, will be required if uses are proposed that would lead to significant exposure of the water compartment

16. REFERENCES

1. National Occupational Health and Safety Commission 1994, *List of Designated Hazardous Substances* [NOHSC:10005(1994)], Australian Government Publishing Service Publ., Canberra.

2. Sax NI & Lewis RJ, 1989, *Dangerous Properties of Industrial Materials*, Van Nostrand Reinhold, New York.

3. National Occupational Health and Safety Commission 1995, 'Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment', [NOHSC: 1003(1995)], in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards*, Australian Government Publishing Service Publ., Canberra.

4. Gobas FAPC, Opperhuizen A & Hutzinger O, 1986, Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation. *Environmental Toxicology and Chemistry* **5**, p 637-646.

5 Baldrick P, 1990, *Acute Oral Toxicity to the Rat of Acrybase FCA-P,* Project number 901268D/FJK 10/AC, data on file, Huntingdon Research Centre, Cambridgeshire.

6. Liggett MP, 1991, *Skin Irritation to the Rabbit of Acrybase FCA-P*, Project number 901278D/FJK 11/SE, data on file, Huntingdon Research Centre, Cambridgeshire.

7. Liggett MP, 1991, *Eye Irritation to the Rabbit of Acrybase FCA-P,* Project number 9173D/FJK 12/SE, data on file, Huntingdon Research Centre, Cambridgeshire.

8. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of Chemicals*, OECD, Paris.

9. 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**.

10. Jones E, 1991, *Acrybase FCA-P: Bacterial Mutation Assay*, Project number FJK 13B/901811, data on file, Huntingdon Research Centre, Cambridgeshire.

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

12. Nabholz JV, Miller P and Zeeman M, 1993, Environmental Risk Assessment of New Substances under the Toxic Substances Control Act Section Five. *In* WG Landis, JS Hughes and MA Lewis (Eds), Environmental Toxicology and Risk Assessment, American Society for Testing and Materials, ASTM STP 1179, Philadelphia. p 40-55.

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

Attachment 1

The Draize Scale 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 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