File No: NA/321

Date: 4th January 1996

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

POLYESTER/STYRENE/ACRYLIC GRAFT POLYMER, RN-230

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Director Chemicals Notification and Assessment

FULL PUBLIC REPORT

POLYESTER/STYRENE/ACRYLIC GRAFT POLYMER, RN-230

1. APPLICANT

Inchape Office Products of 12 Barcoo Street, East Roseville, NSW 2069, has submitted a standard notification for assessment of the polyester/styrene/acrylic graft polymer, RN-230.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, the polyester/styrene/acrylic graft polymer, RN-230, is not considered to be hazardous. Therefore, the chemical name, CAS number, molecular and structural formulae, molecular weight, composition of the polymer, methods of detection and determination and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Other name: RN-230

Molecular weight: >1000

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: pale yellow powder

Odour: none provided

Melting/Softening Point: 133.5-138.5°C

Density: 1130 kg/m³ at 25°C

Vapour Pressure: <6.3 x 10⁻¹⁸ Pa at 25°C (estimated)

Water Solubility: < 10⁻⁵ g/L

at 20°C. The water extractable portion of the polymer RN-230 was determined to be 0.2 g/kg at 20°C (EEC Directive 92.69, A.6 "Water

Solubility" and OECD Draft Guideline: "Solution / Extraction Behaviour of Polymers in Water").

Partition Co-efficient

(n-octanol/water) log Pow: >6 (estimated)

Hydrolysis as a function of pH: not performed **Adsorption/Desorption:** not performed

Dissociation Constant not performed

Flash Point: not performed

Flammability Limits: not highly flammable

Combustion Products: none provided

Pyrolysis Products: carbon oxides and phenol

derivatives

Decomposition Temperature: 330°C

Decomposition Products: none provided

Autoignition Temperature: >350°C

Explosive Properties: none

Reactivity/Stability: relatively stable, avoid contact with

strong oxidising agents or sunlight and temperatures above 40°C.

Particle size distribution: range - <0.150mm 14.7% (w/w)

≥1000mm 7.60% (w/w)

Comments on physico-chemical properties

Determination of the dissociation constant in water according to OECD TG 112 was not possible due to the low solubility of the polymer. Polymer contains some free carboxylic acid groups expected to have typical acidity. The low solubility of the notified polymer prevented the determination of adsorptive/desorptive characteristics according to guidelines in force, for the same reason a hydrolysis study could not be undertaken. The polymer contains no functionalities that are likely to hydrolyse under environmental conditions. On the basis of the notified polymer's low water solubility and high Log Pow, it is likely to adsorb to soil/sediment and organic matter and be immobile in soil. The flash point was not determined as the material is a solid substance which does not melt and decomposes or reacts at about 330°C. The autoignition temperature could not be determined as when heated between 30-350°C no exothermic heat effect that could initiate or sustain combustion was observed

4. PURITY OF THE CHEMICAL

Information exempted at the request of the notifier.

5. INDUSTRIAL USE

The notified polymer will not be manufactured in Australia, but imported as a component of photocopier toners and developers for use in dry process photocopiers. These formulations will be imported in tape sealed cartridges. The level of the notified chemical in toners is 80-85% and in developers 2-3%. The notified polymer is already being imported into Australia under a Commercial Evaluation Certificate, No.168.

The estimated imports of the notified chemical the polyester/styrene/acrylic graft polymer, RN-230 are less than 10 tonnes per annum for the first 5 years.

6. OCCUPATIONAL EXPOSURE

The notified polymer is imported in tape sealed cartridges for ready use in photocopiers. There are two main groups of workers likely to be exposed to the notified polymer. The first is a group of 15-20 service technicians involved in the maintenance and installation of the dry photocopiers. The second group are office workers using the photocopiers. As the machines utilise cartridges the probable exposure to both groups of workers will be low. The service technicians have the potential for the greatest exposure. This will occur if there is a malfunction and or toner/developer escapes from the cartridge. The notifier states that little airborne dust is anticipated due to the relatively large particle size. The particle size distribution partially confirms this as only approximately 15% of the particles are what are considered as inspirable according to the International Organisation for Standardisation and the American Conference of Governmental Industrial Hygienists (1). The Australian exposure standard (1) for nuisance dusts is relevant to the formulations:

TWA 10 mg/m³ for inspirable dust

It should also be noted that there are standards for carbon black and iron oxide; additional components of toners/developers, these are 3 and 5 mg/m³ respectively.

Photocopiers should be operated in well ventilated areas to ensure conformance with these exposure standards. Where work practices and engineering controls are deficient then appropriate personal protective equipment should be used.

7. PUBLIC EXPOSURE

The polyester/styrene/acrylic graft polymer, RN-230 will be imported to Australia as a component of formulated photocopy toners and developers, at levels of 80-85% and 2-3% respectively, in sealed cartridges. The cartridges will be transported by road to end-users, for use in dry process photocopiers. The cartridges will be contained within a compartment of the copying machines. The chemical will be firmly bound to paper in the copying process. In the case of accidental spillage, the chemical is

unlikely to generate substantial airborne dust, and only about 15% of its particles have a respirable diameter. Waste paper containing the chemical will be recycled, disposed to landfill, or incinerated. Public exposure to the notified chemical is accordingly expected to be negligible during its importation, use and disposal.

8. ENVIRONMENTAL EXPOSURE

Release

The notified polymer is a component of a toner that is contained within a cartridge. When the photocopier indicates that it requires more toner, the operator removes a toner cartridge and replaces it with another. Therefore, release of the notified polymer under normal conditions of use is expected to be negligible, as practically no waste is generated.

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

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

Release 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 groundwater. Its low water solubility and high Log Pow 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 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 polymers expected persistence.

Paper recycling is a growing industry in Australia. Waste paper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance the fibre separation, ink detachment from the fibres, pulp brightness and the 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 hydrolysis of ester linkages under alkaline conditions will be minimal due to the very low solubility of the polymer. The polymer therefore is likely to survive the paper recycling conditions, either remaining bound to the pulp or becoming associated with the sludge. In the latter case, the polymer will

arrive in landfill where it can be expected to remain intact, or be destroyed through incineration.

9. EVALUATION OF TOXICOLOGICAL DATA

For a synthetic polymer with number average molecular weight (NAMW) > 1000 toxicology data is not required under the Act. However the following data was included with the submission and is reproduced here for information:

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of RN-230

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD ₅₀ >2000mg/kg	(2)
Skin Irritation	Rabbit	Not irritant	(3)
Skin sensitisation	Guinea-pig	Non-sensitiser	(4)

9.1.1 Oral Toxicity (2)

Number/sex of animals: 5/5 Observation period: 14 days

Method of administration (vehicle): orally by gavage in arachis oil

Clinical observations: No signs of systemic toxicity were noted during the study.

Morphological findings:

No abnormalities

detected

Test Method: Directive 84/449/EEC, B.1 OECD Guideline No.401.

9.1.4 Skin Irritation (3)

Result: Non-irritant, (very slight erythema but not persistent) Species/strain: New

Zealand White rabbit

Number/sex of animals: 2m/1f

Method of administration: 500mg of test substance semi-occlusive dressing

Test Method: In compliance with Japanese Ministry of health and Welfare,

Notification No. Yakuhatsu 124, Pharmaceutical Affairs Bureau,

11/9/1989.

Draize (5) Scores¹

¹ Draize Scale for evaluation of skin reactions is as follows:

Animal	Time after decontamination				
	30-60 min	1 day	2 days	3 days	
ERYTHEMA					
1	1	0	0	0	
2	1	0	0	0	
3	1	0	0	0	
OEDEMA					
1	0	0	0	0	
2	0	0	0	0	
3	0	0	0	0	

9.1.6 Skin Sensitisation (4)

Result: Non-sensitiser

Species/strain: Hartley Albino Guinea Pig

Number of animals: Experimental group: 10 females

Control group: 10 females

Induction: Intradermal induction: 3% (w/w) in liquid paraffin

6% (w/w) in Freund's complete adjuvant

+ liquid paraffin (1:1)

Topical induction: 50% (w/w) in liquid paraffin Topical challenge 50% (w/w) in liquid paraffin

Results:

Challenge	24 hrs		48hrs	
Concentration	test	control	test	control
50%	0/10	0/10	0/10	0/10

Test Method: OECD Guideline No. 406, 1981

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (6)

Erythema Formation	rating	Oedema Formation r	ating
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 2
Moderate to severe erythema	3	by definite raising) Moderate oedema (raised approx. 1mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm a	nd 4
		extending beyond area of exposure)	

Result: No significant increases in the number of revertant colonies of bacteria were recorded for any of the strains of bacteria used, at any dose level, either with or without metabolic activation. No toxicity exhibited to any of the strains of bacteria used.

Strains: Salmonella typhimurium TA 1535, TA 1537, TA 1538, TA98, TA100 and Escherichia coli WP2 uvrA

Concentration range: 312.5 - 5000µg/ plate

Test Method: OECD Guideline No. 471, directive 92/69/EEC, B.14

9.4 Overall Assessment of Toxicological Data

The notified chemical was of low oral toxicity to rats(LD₅₀>2000 mg/kg). The polyester/styrene/acrylic graft polymer, RN-230 is not a skin irritant in rabbits or a skin sensitiser in guinea pigs. RN-320 was non-mutagenic *in vitro* to *Salmonella typhimurium* strains TA 1535, TA 1537, TA 1538, TA98, TA100 and *E.coli* WP2 *uvrA*.

On the basis of the available toxicological data the notified chemical, polyester/styrene/acrylic graft polymer, RN-230 would not be classified as hazardous according to the criteria of Worksafe Australia (7).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW > 1000 according to the Act.

The notified polymer is not likely to exhibit toxic characteristics in the environment because large polymers of this nature are not readily absorbed by biota.

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 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 negligible hazard as it will be marketed in cartridges for direct insertion into the photocopier machine.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Synthetic polymers of NAMW > 1000 as a rule tend to not be biologically active for this reason toxicological data is not normally required as specified in the *Act*.

Occupational exposure to the notified chemical and consequential health and safety effects would be limited for a number of reasons:

- Only the formulated product is imported into Australia, there is no reformulation or manufacture locally. Formulations will contain from 2- 85% of the notified chemical.
- The formulation is imported in tape sealed cartridges for direct use in photocopiers.
- The physico-chemical properties of the notified chemical (including particle size, solubility, molecular weight and reactivity) mean that exposure and risk will be limited.
- The chemical is unlikely to be acutely toxic, to be a skin irritant, skin sensitiser and is unlikely to be genotoxic.

The eye irritation potential and inhalation toxicity of RN-320 have not been assessed. The particle size distribution indicates that the notified chemical may be a physical eye irritant. The particle size distribution indicates that only a small percentage of the notified chemical would be respirable. However without inhalation toxicity data the effects cannot be readily assessed.

Public exposure is expected to be negligible during the importation, use and disposal of the notified chemical.

13. RECOMMENDATIONS

To minimise occupational exposure to the polyester/styrene/acrylic graft polymer, RN-230, the following guidelines and precautions should be observed:

- if engineering controls and work practices are insufficient to reduce exposure to the polyester resin, EPB 90/0/01, to a safe level, then personal protective devices which conform to and are used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (8,9). The appropriate respiratory device should be selected and used in accordance to Australian Standard/New Zealand Standard (AS/NZS) 1715 (10) and should comply to AS/NZS 1716 (11);
- a copy of the Material Safety Data Sheet should be easily accessible to employees.
- . Implement good work practices to avoid the generation of dusts; avoid spillage.
- . Good general and local exhaust ventilation should be provided in photocopying areas.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for the polyester/styrene/acrylic graft polymer, RN-230 was provided in Worksafe Australia format (12).

This MSDS was provided by Inchape Office Products as part of their notification statement. The accuracy of this information remains the responsibility of Inchape Office Products.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals* (*Notification and Assessment*) Act 1989, secondary notification of the polyester/styrene/acrylic graft polymer, RN-230 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

- 1. National Occupational Health and Safety Commission, 1995. *Exposure standards for atmospheric contaminants in the occupational environment,* AGPS, Canberra.
- 2. Driscoll R, 1993. RN-230: *Primary skin irritation test in the rabbit.* Safepharm Laboratories, Derby, U.K., Project No: 140/241.
- 3. Driscoll R, 1993. *RN-230: Acute oral toxicity (limit test) in the rat.* Safepharm Laboratories, Derby, U.K., Project No: 140/224.
- 4. Kanokozawa W, 1994. *The maximisation test for contact hypersensitivity potential of RN-230 in guinea pigs.* Saitama Institute, Drug Safety testing Centre Co. Ltd. Saitama, Japan, Test Number 9326.
- 5. 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.
- 6. Safepharm Laboratories, 1993. RN-230: Six strain reverse mutation assay "Ames test" using Salmonella typhimurium and Escherichia coli. Safepharm Laboratories, Derby, U.K., Project No: 140/243.
- 7. National Occupational Health and Safety Commission, 1994, *Approved Criteria for Classifying hazardous Substances [NOHSC:1008(1994)]*, AGPS, Canberra.
- 8. Standards Australia, 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia.
- 9. Standards Australia, Standards New Zealand 1992, Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications, Standards

- Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.
- 10. Standards Australia, Standards New Zealand, 1994. *Australian/New Zealand Standard 1715 1994 Selection, Use and Maintenance of Respiratory Protective Devices.* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ., Wellington, New Zealand.
- 11. Standards Australia/ Standards New Zealand, 1991. *Australian/New Zealand Standard 1716 1991 Respiratory Protective Devices*. Standards Association of Australia Publ., Sydney, Australia.
- 12. National Occupational Health and Safety Commission, 1990, *Guidance Note for the Completion of a Material Safety Data Sheet,* 2nd. edition, AGPS, Canberra.