File No: PLC/130

March 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Polymer in RPE-130

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Polymer in RPE-165

1. APPLICANT

Ricoh Office Automation Pty Ltd of 8 Rodborough Road FRENCHS FOREST NSW 2088 and Lanier (Australia) Pty Ltd of 854 Lorimer Street PORT MELBOURNE VIC 3207 have submitted a Polymer of Low Concern (PLC) notification statement in support of their application for an assessment certificate for Polymer in RPE-165.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report.

Marketing Name:	Polymer in RPE-165
Method of Detection and Determination:	ultraviolet/visible (UV/Vis) spectrophotometry, infrared (IR) spectroscopy and nuclear magnetic resonance (NMR) spectroscopy

Characterisation as a Synthetic Polymer of Low Concern

Number-Average Molecular Weight (NAMW):	> 1 000
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	< 10%
Molecular Weight < 1 000:	< 25%
Polymer Stability	under normal conditions of storage and use the notified polymer is not expected to undergo degradation; >200°C it will degrade to oxides and hydrocarbons
Reactivity	notifier indicates that the polymer will react with oxidising material
Charge Density	not applicable the notified polymer is not cationic

The polymer meets the criteria for assessment as a synthetic polymer of low concern under Regulation 4A of the *Industrial Chemicals (Notification and Assessment) Act 1989.*

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	light yellow granules
Melting Point:	180°C (see comments below)
Density:	1 200 kg/m^3
Vapour Pressure:	not applicable
Water Solubility:	< 0.1mg/L (see comment below)
Partition Co-efficient (n-octanol/water):	not applicable
Hydrolysis as a Function of pH:	not determined (see comments below)
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined (see comments below)
Flash Point:	not applicable
Flammability Limits:	not determined
Autoignition Temperature:	not applicable°C
Explosive Properties:	not explosive
Reactivity/Stability:	stable under normal conditions of storage and use; degrades at temperatures > 200°C to oxides and hydrocarbons

Particle Size (for the toner): Number Average Diameter = 6.02 μm
Weight Average Diameter = 9.37 μm

Particle size distribution

Diameter (μm)	*Weight %*
2.00-2.52	0.06
2.52-3.17	0.27
3.17-4.0	1.01
4.00-5.04	3.57
5.04-6.35	9.41
6.35-8.0	16.88
8.00-10.1	25.69
10.1-12.7	23.82
12.7-16.0	12.84
16.0-20.2	4.74
20.2-25.4	0.97
25.4-32.0	0.21
32.0-40.3	0.00
40.3-50.8	0.52

Comments on Physico-Chemical Properties

The water solubility was tested by adding 300 mL of deionised water to 3 weighed samples of polymer and shaking the flasks for 24 h at 20ºC. The samples were then filtered, dried and weighed, the % solubility was calculated from the difference between the 'before' and 'after' weights.

Hydrolysis of the ester and ether linkages of the polymer would not be expected under environmental conditions.

On the basis of the polymer's low water solubility it is likely to have a high log P and 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: high

Toxic or Hazardous Impurities: none known

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. Polymer in RPE-165 will be imported as a component (greater than 50%) of a fully formulated toner product ready for use in photocopying equipment. The notified polymer will act as a binder to fix toner particles to the paper. In the first year, 2.5 tonnes of the notified polymer will be imported rising up to 7.4 tonnes in five years.

6. OCCUPATIONAL EXPOSURE

The notified polymer will be imported as a component of printer toner and will be contained in cartridges. Waterside, warehouse and transport workers (estimated to be 4-6 workers) handling the toner for 2 to 3 hours/day, 50 days/year are unlikely to be exposed to the notified chemical except in the event of an accident.

Approximately 100 customer service engineers will maintain photocopiers. As part of the maintenance they will be required to change the toner cartridge and waste toner bottles. Changing toner cartridges involves removal of the old cartridge and directly loading the new cartridge to the photocopier. The pre-packaged cartridges are sealed and exposure to the notified polymer should be minimised through use of the replacement procedures recommended by the manufacturer. The toner cartridges are designed so that no release of the contents can occur until a shutter or seal tape is removed. However, dermal, occular and inhalation exposure may occur if toner is spilt while changing cartridges. The notifier states that service engineers are required to wear cotton gloves during maintenance operations, if direct contact with the toner is likely. The service engineers may spend up to 5 to 20 minutes/day, 200 days per year in maintenance operations.

It is unlikely that the office workers using the photocopiers will be exposed on a regular basis to the notified polymer as they will not be involved in maintenance operations. Most exposure would be to the notified polymer on the printed paper. As the polymer is bound to the paper, dermal exposure to it will be negligible.

7. PUBLIC EXPOSURE

There is negligible potential for exposure of the public to the notified polymer. The notified polymer will be a component of sealed toner cartridges for photocopiers. Exposure of the general public to the notified polymer is only likely through contact with printed paper containing the dried bound polymer. The most likely scenario in which the public could be exposed more directly to the notified polymer is in the event of a transport accident where the risks to public health are assessed to be relatively low.

8. ENVIRONMENTAL EXPOSURE

Release

The notified polymer will be imported as a component of printer toner and will be contained in cartridges. The toner cartridges are fully sealed prior to insertion into copier machines and therefore minimal environmental release is expected prior to use. When the toner is exhausted, the used cartridges are discarded to landfill via commercial disposal. The notifier estimates approximately 4% (296 kg/annum) of the notified polymer will remain as residue in spent cartridges.

Photocopiers designed to use these cartridges possess a waste toner bottle which, when full, is discarded and ultimately ends up in landfill. Approximately 10% (740 kg) of the import volume of the notified chemical will be released in this way.

Release of the notified polymer is expected to occur at landfill sites where spilt material and waste paper are discarded. In addition, polymer removed from the paper during recycling is likely be incorporated with the waste sludge which will be discarded to landfill or incinerated.

Potential release of the polymer may occur as a result of transport accidents but these losses would be expected to be only minor as the toner is packaged into the individual cartridges. Collection of spilt material will be disposed of to either landfill or incineration.

Fate

During recycling, waste paper is pulped and de-inked using a variety of dispersing and wetting agents, organic solvents and bleaches. After pulping, the contaminants and ink are separated from the fibres by pumping the stock through various heat washing, screening, cleaning, flotation and dispersion stages. During these processes there is the potential for hydrolysis of the polymer to occur. Polymer removed from the paper will most likely be incorporated with the sludge remaining from recycling. Sludge is likely to be discarded to landfill or incinerated. Combustion products from incineration are likely to be water and oxides of carbon and hydrogen.

Once in landfill, leaching of the toner/polymer mix is unlikely due to the low solubility of the substance. Hydrolysis, although theoretically possible, is unlikely.

Polymer accidentally entering waterways would be expected to settle out onto sediments. The polymer is not expected to cross biological membranes, due to the low solubility and high molecular weight. Therefore the notified substance is not expected to bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

The polymer has been notified as a PLC. Part C of the schedule is not required, however available data should be submitted. The notifier has submitted a report of one toxicological test, which is summarised below.

9.1 Acute Toxicity

Summary of the acute toxicity of the notified polymer

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50}>2000 mg/kg	(Driscoll,1998)

9.1.1 Oral Toxicity (Driscoll, 1998)

Species/strain:	Rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	A dose of 2000 mg/kg of test substance in arachis oil was administered by gavage.
Test method:	OECD TG 401
Mortality:	No deaths were recorded over the observation period.
Clinical observations:	No clinical signs of toxicity were noted.
Morphological findings:	No abnormalities were noted.
LD_{50}:	>2 000 mg/kg
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.2 Overall Assessment of Toxicological Data

The notified polymer was of low oral (LD_{50} > 2 000 mg/kg) toxicity when tested in rats.

On the basis of the submitted data, the notified chemical would not be classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

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

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.

Accidental spillage of the polymer, either during replacement of cartridges or during transport should result in powder wastes being sent to either landfill or incineration facilities. Movement of the polymer by leaching from landfill sites is not expected.

Environmental exposure to the notified substance could occur when paper containing the polymer is recycled or disposed of. The polymer would remain either bound to waste paper, or to sludge that results from recycling processes.

The toner residues remaining in the 'empty' cartridges and waste toner bottle will be disposed of to landfill with the spent cartridges and bottles where it should remain until slowly degraded by biological and bacteriological processes.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer was of very low acute oral toxicity. Data are not available on skin and eye irritation and the effects of repeated or prolonged exposure. The acute dermal toxicity of the notified polymer is not known, but is expected to be low given the high molecular weight, small percentage of low molecular weight species, and low acute oral toxicity. Whilst no inhalation studies were conducted, based on the particulate size (57.43% within respirable range < 10 μm and 100% within inspirable range < 185 μm) it may cause respiratory irritation in the event of accidental exposure. The notified polymer is not classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) based on the limited available data.

Occupational Health and Safety
Waterside, warehouse and transport workers will be only be exposed to the notified polymer in the event of an accident or damage to packaging. The occupational health risk to these workers is negligible.

Office workers are not expected to come into substantial contact with the notified polymer under normal circumstances. Dermal contact with printed paper will occur but exposure and uptake of the polymer will not occur because it is bound to the paper. Hence, the health risk to these workers is negligible.

Customer service engineers who maintain photocopiers will change toner cartridges and change waste bottles. Exposure is expected to be of short duration, yet frequent. There will not be extensive handling of the toner cartridge during changing operations and spillages are not expected if recommended work practices are followed. It is recommended that these workers wear cotton gloves where contact with the toner is likely and that photocopiers are placed in well ventilated areas. Instructions for changing the cartridge is given on the end use product label. In the event of a spill, service engineers may be exposed to the notified polymer by dermal or respiratory routes. In this case, inhalation exposure to the notified polymer may be high, as it makes up large percentage of the final toner product. In addition, 57.43% of the toner particles falls within the range considered respirable (< 10 μm) under NOHSC (National Occupational Health and Safety Commission, 1995).

Based on the low toxicological hazard presented by the notified polymer, the nature of work done and containment of toner in cartridge, risk to service engineers is expected to be low.

There is a NOHSC exposure standard of 3 mg/m^3 8 hour time weighted average (TWA) for carbon black (NOHSC, 1995), identified as an ingredient in the product Material Safety Data

Sheet (MSDS). The employer is responsible for ensuring that this exposure standard is not exceeded in the workplace.

Public Health
There is low potential for public exposure to the notified polymer arising from its use as a component in toner cartridges in photocopiers. The notified polymer is bound to printed paper rendering it effectively inert.

13. RECOMMENDATIONS

Occupational Health and Safety
To minimise occupational exposure to Polymer in RPE-165 the following guidelines and precautions should be observed:

- Work areas around photocopiers 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;
- Spillages should be swept or picked up by vacuum and residue removed with soap and water;
- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

Public Health
If the conditions of use are varied from the notified use, greater exposure of the public to the product may occur. In such circumstances, further information may be required to assess the hazards to public health.

14. MATERIAL SAFETY DATA SHEET

MSDS for products containing the notified chemical were provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

These MSDS were provided by the applicants 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 applicants.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(1) of the Act, secondary notification will be required if the polymer

characteristics cease to satisfy the criteria under which it has been accepted as a Synthetic Polymer of Low Concern. Secondary notification of the notified polymer 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

Driscoll, P. 1998, Polymer in RPE-165*:* Acute Oral Toxicity (Limit Test) in the Rat, Project no., 748/191, Safepharm Laboratories Limited, UK.

National Occupational Health and Safety Commission 1999, Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)], Australian Government Publishing Service, Canberra.

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.

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.

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