File No: EX/8 (NA/392)

June 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PI-6100
(also known as T-C-002)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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, National Occupational Health and Safety Commission, 92-94 Parramatta Road, Camperdown NSW 2050, between the following hours:

Monday - Wednesday	8.30 am - 5.00 pm
Thursday	8.30 am - 8.00 pm
Friday	8.30 am - 5.00 pm

Copies of this full public report may also be requested, free of charge, by contacting the Administration Coordinator on the fax number below.

For enquiries please contact the Administration Coordinator at:

Street Address: 92 Parramatta Rd Camperdown, NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, Sydney 2001, AUSTRALIA
Telephone: (61) (02) 9577-9514 FAX (61) (02) 9577-9465

Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PI-6100
(also known as T-C-002)

1. APPLICANT

First Applicant

An Assessment Certificate (Certificate No: 000553, Date: 9 April 1997,) for the notified chemical known by the trade name PI-6100 was granted to Tomen Australia Ltd of Level 50 Rialto 525 Collins Street MELBOURNE VIC 3000.

The Assessment Report for PI-6100 is identified by the sequence number NA/392.

Second Applicant

Since granting of the abovementioned Assessment Certificate, Mita Copiers Australia Pty Ltd of 25 Sirius Road LANE COVE NSW 2066 has submitted a notification statement in support of their application for an extension of the Assessment Certificate for PI-6100. The trade name adopted by Mita Copiers for the said polymer is T-C-002.

Tomen Australia Ltd has agreed to this extension.

New information on the new chemical in this current application submitted by Mita Copiers Australia Pty Ltd, pertains to the identity of the chemical and import volume. In addition, in support of their application Mita Copiers has provided toxicity data on the toner product that contains the notified polymer. The original assessment report (NA/392) has been amended to incorporate this new information.

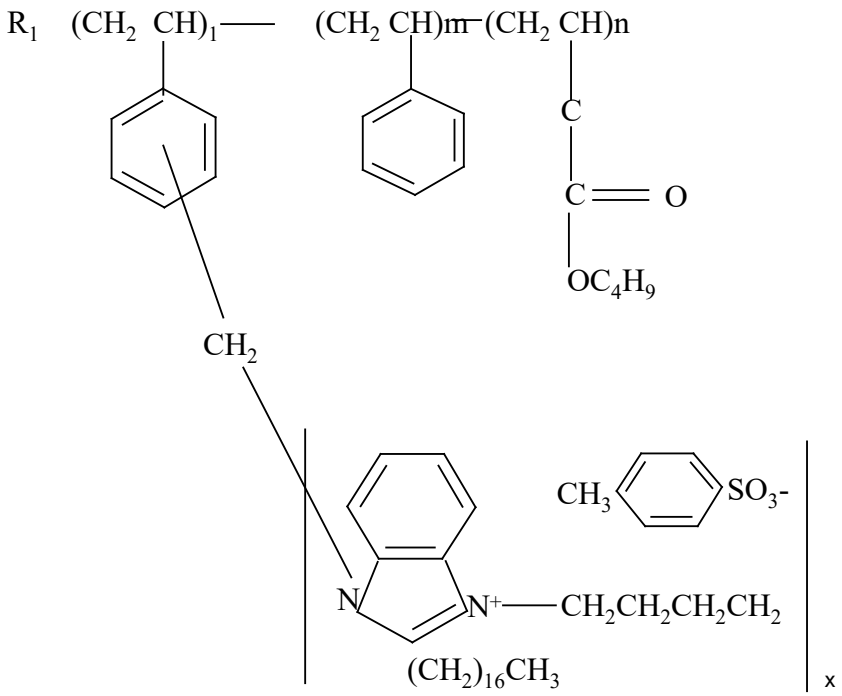
There are, however, no changes in information since the original notification statement submitted by Tomen Australia Ltd, in matters affecting occupational, environmental or public exposure.

2. IDENTITY OF THE CHEMICAL

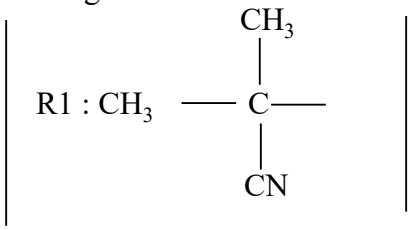
Notifier has not requested any information to be considered confidential.

Chemical Name:	2-propenoic acid, butyl ester, polymer with (chloromethyl) ethenylbenzene, 1,4-dibromobutane, ethenylbenzene and 2-heptadecyl-1H-benzimidazole, graft compd. with sodium 4-methylbenzenesulfonate
Chemical Abstracts Service (CAS) Registry No.:	154099-14-6
Other Names:	benzimidazole, 2-heptadecyl-, polymer with 1,4-dibromobutane and (chloromethyl) ethenylbenzene polymer with ethenylbenzene and butyl 2-propenoate, ion exchanged with sodium 4-methylbezenesulfonate
Trade Names:	PI-6100 T-C-002
Molecular Formula:	$(C_7H_{12}O_2 \,.\, C_9H_9Cl \,.\, C_4H_8Br_2 \,.\, C_8H_8 \,.\, C_{24}H_{40}N_2 \,.\, C_7H_7O_3\ SNa)_x$

Structural Formula:



R1:initiator fragment



1:m:n = 1≅ 5 : 65 ≅ 94 : 5 ≅ 30 (mole ratio)
x = 5 ≅ 30 (degree of polymerisation

Molecular Weight:

Number-Average Molecular Weight: 17 800

Weight-Average Molecular Weight: not provided

Maximum Percentage of Low Molecular Weight Species
Molecular Weight < 500: 0.1%
Molecular Weight < 1000: 0.23%

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*
1 H-benzimidazole, 2-heptadecyl-	5805-27-6	24.1%
butane, 1,4-dibromo-	110-52-1	12.9%
benzene (chloromethyl) ethenyl-	30030-25-2	1.7%
benzene, ethenyl-	100-42-5	41.6%
2-propenoic acid, butyl ester	141-32-2	5.1%
propanenitrile, 2,2'-azobis[2-methyl-	78-67-1	1.0%
benzenesulfonic acid, 4-methy-, sodium salt	657-84-1	13.6%

Method of Detection and Determination: the notified chemical is identified by nuclear magnetic resonance (NMR) and infrared (IR) spectroscopy and quantitatively determined by ultraviolet/visual (UV/Vis)spectral analysis

Spectral Data:

UV/Vis: in 1,2-dichloroethane at a concentration of 0.1 g/L, peak at 268 nm and in N,N dimethylformamide at a concentration of 0.101 g/L, peak at 255 nm

IR (Kbr disk) : major characteristic peaks were observed at 1730, 1500, 1450, 1100, 900, 800, 700 and 600 cm^{-1}

NMR: a proton NMR spectrum was provided and was consistent with the expected structure of the chemical

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	light brown granules
Softening Point:	110°C (at 760 mm Hg)
Density:	1040 kg/m^3
Vapour Pressure:	1 x 10^{-2} kPa at 25°C
Water Solubility:	< 3 mg/L at 25°C
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	see comment below
Adsorption/Desorption:	not determined
Dissociation Constant:	not determined
Flash Point:	230°C
Flammability Limits:	non-flammable
Autoignition Temperature:	388 ± 5°C
Explosive Properties:	not explosive
Reactivity/Stability:	not reactive
Particle Size:	0.6% = 75-45 μm 1.6% = 90-75 μm 4.6% = 180-190 μm 12.9% = 355-180 μm 80.0% > 355 μm

Comments on Physico-Chemical Properties

No information was supplied regarding boiling points. It is unlikely that the substance will boil under ambient conditions and therefore the omission of such data is acceptable.

The vapour pressure was measured using the vapour pressure balance method according to EEC Directive 67/548, Annex V.A4.

Water solubility test was conducted by a method similar to OECD test guideline 105 (shake flask method). Total Organic Carbon Analysis and gravimetric analysis were used to

determine the solubility.

The polymer was tested for hydrolysis in the pH range of 1.2 - 9.0 using OECD test guideline 111 and found to be hydrolytically stable under test conditions. The molecule contains potentially hydrolysable ester functionalities, but it is not expected to undergo hydrolysis in the environmental pH range. The molecule also contains quaternary ammonium functionality which may exchange the counter anion under certain pH conditions.

Results for partition coefficient, adsorption/desorption, and dissociation constants were not provided, as the low solubility of the substance prevented testing of these characteristics. Based on the notified polymer's low water solubility it is likely to adsorb to soil/sediment and organic matter or be immobile in soils.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

Toxic or Hazardous Impurities:

Chemical name:	benzene, ethenyl
Synonyms:	styrene, cinnamenol
CAS No.:	100-42-5
Weight percentage:	0.03%
Toxic properties:	mildly toxic to humans by inhalation; suspected human carcinogen and a teratogen; at 200 ppm lacrimation and severe eye injury in humans; a human skin irritant; an experimental skin and eye irritant (1)

Chemical name:	2-propenoic acid, butyl ester
Synonyms:	acrylic acid butyl ester, butyl acrylate
CAS No.:	141-32-2
Weight percentage:	0.02%
Toxic properties:	oral rat LD_{50} = 900 mg/kg; moderately toxic by ingestion; a skin and eye irritant (1)

Chemical name:	propanenitrile, 2,2' - azobis[2-methyl-]
Synonyms:	azobisisobutylonitrile, azodiisobutyonitrile
CAS No.:	78-67-1
Weight percentage:	0.01%
Toxic properties:	oral-rat LDL_O = 670 mg/kg; moderately toxic by ingestion (1)

Chemical name:	succinonitrile tetramethyl
Synonyms:	TMSN
CAS No.:	3333-52-6
Weight percentage:	0.01%
Toxic properties:	oral ral LD_{50} = 60 mg/kg; an experimental teratogen; experimental reproductive effects (1)

Chemical name:	benzenesulphonic acid, 4-methyl-sodium salt
Synonyms:	sodium p-tolyl sulfonate
CAS No.:	657-84-1
Weight percentage:	0.1%
Toxic properties:	moderately toxic by intravenous route (1)

Chemical name:	formamide, N,N-dimethyl-
Synonyms:	dimethyl formamide, DMFA
CAS No.:	68-12-2
Weight percentage:	0.2%
Toxic properties:	a skin and eye irritant; experimental teratogen (1)

Chemical name:	sodium bromide
Synonyms:	bromnatrium
CAS No.:	7647-15-6
Weight percentage:	0.2%
Toxic properties:	moderately toxic by ingestion; experimental reproductive effects (1)

Non-Hazardous Impurities
(> 1% by Weight): none

Maximum Content
of Residual Monomers: < 0.48%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia, but imported at a rate of 1 to 10 tonnes per annum for the next five years, as a pure chemical or as a component (4%) of formulated electrographic toner for use as a charge control agent in dry process photocopiers/printers. The notifier claims that the polymer will be imported, initially as a component in the formulated toner in sealed cartridges.

In the application for extension, the notified polymer will be imported as a ready-to-use toners for photocopiers contained in tape sealed cartridges. The import volume for the notified chemical is estimated to be in the range of 100 to 200 kg per annum in the first 5 years.

6. OCCUPATIONAL EXPOSURE

Each cartridge contains 100 to 1 000 g of the toner. The cartridges will be packed in cardboard boxes and shipped in 20 foot long containers to Australia. There is low probability of exposure during transport and handling in the event of an accident.

There are two types of workers who are likely to be exposed to the notified polymer: photocopier users replacing toner cartridges, once every few weeks per machine; and workers who are involved in the formulation of the toner. The toner in the photocopier is recharged by removal of the cartridge and discarding to a plastic bag and loading the prepacked toner cartridge to the photocopier. Exposure is expected to be low given that each recharge takes about five minutes by a photocopier user.

Typically, formulation involves first charging the mixing vessel with the notified polymer (200 kg/day) with other components (binder resin, carbon black, polypropylene wax and recycled fine powder) carried out under local exhaust ventilation with bagfilter. The mix produced, is then transfered to a kneader, by means of a closed type automatic feeder to form into a uniform product. This is transfered to a hammer mill, and then to a jet mill through closed type automatic feeders under local exhaust ventilation or exhaust through cyclone and bagfilters. The toner product is mixed with colloidal silica under local exhaust ventilation and packed into cartridges using a closed type automatic bottler. The fine powder collected from the classifier is recycled. The notifier claims that the maximum amount of the polymer released during the formulation process will be less than 0.009 kg/day.

The formulating process is undertaken in well ventilated areas, overseen by 10 operators

(approximate exposure 8 hours/day) in a typically automated working environment.

7. PUBLIC EXPOSURE

There exists little possibility for public exposure to the notified chemical during normal use of the photocopier or by exposure to the photocopied pages. The potential for minor public exposure to the chemical exists during transport, disposal of chemical if accidentally spilt and disposal of used cartridges. This is minimised by the recommended practices during transportation and waste disposal.

8. ENVIRONMENTAL EXPOSURE

Release

Practically no waste is generated under normal conditions during the formulation of the toner using the notified chemical. It is estimated that only a very small amount of the polymer will be released to the environment during the formulation process, with dust collectors/air filters limiting the release to the environment. After formulation, the toner is packed in a cartridge and distributed for use in photocopiers.

When the photocopier indicates that it requires more toner, the operator removes a toner cartridge and replaces it with another. This operation is likely to be carried out one to two times per month. It is estimated that 5 g of toner (200 mg of the notified polymer) would remain in the used cartridge. Therefore, the disposal of used toner cartridges is not expected to release significant quantities of the notified polymer into the environment. The used toner cartridge and any spills of toner can be disposed of as domestic waste, in accordance with government regulations (eg landfill, incineration).

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

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 indicates it is unlikely to leach.

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

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.

If the polymer were spilt to waterways, it would not be expected to disperse into the water column, but should 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 should not bioaccumulate.

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 where it can be expected to remain intact, 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) greater than 1 000, although the data summarised below were submitted by the original applicant.

9.1 Repeated Dose Toxicity (2)

Species/strain:	Rat/Crl:CD®(SPF)
Number/sex of animals:	6/sex in control and dose groups
Test Substance	toner product containing the notified polymer at a concentration of 1 to 5%.
Method of administration:	orally (gavage)
Dose/Study duration::	(two) control, low, mid and (two) high dose groups treated by gavage at doses of 0, 30, 300 or 1 000 mg/kg/day; treatment continued for 28-days with a 14 day recovery period for the control and high dose groups
Clinical observations:	no clinical signs of toxicity observed in any of the animals
Clinical chemistry/Haematology	the treatment had no influence on the haematology profile apart from a high value of erythrocytes in a female of the lowest dose group, the extent of increase in this case was considered to be within physiological variations

Histopathology:	dark reddish patches in the stomach of 4 animals in the high dose group and in the recovery group. It is possible that the lesion was due to stress induced by dosing
Test method:	OECD Guidelines for Testing of Chemicals (3)
Result:	no evidence of systemic toxicity following sub-acute dosing in the rat

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (4)

Strains:	TA 98, TA 100, TA 1535, TA 1537 and *WP2 uvrA*
Test Substance	notified polymer
Concentration range:	156 - 5 000 μg/plate
Test method:	OECD Guidelines for Testing of Chemicals (3)
Result:	not mutagenic in the bacterial strains tested, in the presence or absence or metabolic activation provided by rat liver S9 fraction

9.2.2 In *Vitro* Cytogenetic Assay in Chinese hamster Cells (5)

Cell Culture:	Chinese hamster CHL/IU cells in RPMI-1640 tissue culture medium, 48 hour growth prior to treatment
Test Substance	notified polymer
Doses:	0, 1 250, 2 500 and 5 000 μg/ml (with or without metabolic activation) for 6 hours (recovery period 18 hours)
Test method:	OECD Guidelines for Testing of Chemicals (3)
Result:	there was no significant increase in the number of cells with structural chromosomal aberrations or polyploid cells with or without metabolic activation; no clastogenic activity observed under the test conditions

In support of their certificate extension application, the second applicant has provided toxicity data on the toner product that contains the notified polymer (less than 5%).

9.3 Acute Toxicity

Summary of the acute toxicity of the toner product containing the notified polymer at a concentration of 1 to 5%.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	not stated	LD_{50} > 2 000 mg/kg	MSDS
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(6)
acute inhalation toxicity	rat	LC_{50} (4 hour) > 5.18 mg/L	(7)
skin irritation	rabbit	non-irritant	(8)
eye irritation	rabbit	mild irritant	(9)
skin sensitisation	guinea pig	non-sensitiser	(10)

9.3.1 Oral Toxicity

The notifiers MSDS for the toner product containing the notified polymer reports an LD_{50} of > 2 000 mg/kg for acute oral toxicity. The full study was not provided.

9.3.2 Dermal Toxicity (6)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Test Substance	toner product containing the notified polymer at a concentration of 1 to 5%.
Dose:	2 000 mg/kg
Method of administration:	single administration of neat test material held under semi-occlusive dressing; after 24 hours residual test material was wiped away with cotton wool moistened with arachis BP oil
Clinical observations:	no signs of systemic toxicity
Test method:	limit test, OECD TG 402 and EEC Method B3 (3)
Mortality:	nil
Morphological findings:	no abnormalities detected
Comment:	no dermal irritation was observed in any animal tested; black staining was noted on the treatment site of all animals on days 1 and 2
LD_{50}:	> 2 000 mg/kg

Result:	the toner product was of low acute dermal toxicity in rats

9.3.3 Inhalation Toxicity (7)

Species/strain:	rat/Sprague-Dawley CD
Number/sex of animals:	5/sex
Observation period:	14 days
Test Substance	toner product containing the notified polymer at a concentration of 1 to 5%.
Dose:	mean achieved atmosphere concentration: 5.18 mg/L (aerosol)
Method of administration:	single, nose-only exposure to an atmosphere of the test material for 4 hours;
Particle size analysis in animal breathing zone:	mean mass median aerodynamic diameter: 7.0 μm; inhalable fraction, (% less than 4 μm): 30.9
Test method:	OECD TG 403 and EEC Method B2 (3)
Mortality:	one male found dead three hours after commencement of exposure
Clinical observations:	during exposure: wet fur, increased respiratory rate and test material staining and occasional signs of laboured respiration and decreased respiratory rate were observed in all animals during exposure; on removal from the chamber: surviving animals showed additionally hunched posture, pilo-erection and occasional or isolated incidents of gasping respiration, ataxia and ptosis; one hour post-exposure: wet fur and laboured respiration had diminished while signs of gasping and noisy respiration, lethargy, ptosis and ataxia increased day 1: signs of toxicity (hunched posture, pilo-erection, increased or decreased respiratory rate and laboured and/or noisy respiration), particularly in males, persisted; all surviving had recovered to appear normal by day 5
Morphological findings:	all animals including the male that died in-study showed dark patches on the lungs; the animal that died also showed abnormal lungs and congestion in the small intestine; one

	female had pale kidneys
LC_{50}:	> 5.18 mg/ L /4 hour (mean achieved atmosphere concentration)
Result:	the toner product was of very low acute inhalation toxicity in rats

9.3.4 Skin Irritation (8)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	3 days
Test Substance	toner product containing the notified polymer at a concentration of 1 to 5%.
Method of administration:	500 mg of the test substance moistened with 0.5 mL of distilled water applied to shorn, intact skin and held under semi-occlusive dressing; after four hours, residual test material was swabbed away with 74% industrial grade methylated spirits
Comment:	no evidence of skin irritation was noted during the study; all Draize scores were zero
Test method:	OECD TG 404 (3)
Result:	the toner product was not irritating to the skin of rabbits

9.3.5 Eye Irritation (9)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 males

Observation period: 3 days

Test Substance toner product containing the notified polymer at a concentration of 1 to 5%.

Method of administration: 0.1 mL (approximately 60 mg)of the test substance instilled into the conjunctival sac of the right eye, the left eye served as the control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***24 hours***			***48 hours***			***72 hours***		
Cornea	***o***		***a***	***o***		***a***	***o***		***a***	***o***		***a***
	no opacity noted											
Iris												
	normal appearance											
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	1	0	0	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Comment: residual test material was noted around all treated eyes throughout the study;
no corneal or iridial effects;
minimal conjunctival redness was noted in one treated eye one hour after treatment and persisted in this eye at the 24 hour observation period

Result: the toner product was slightly irritating to the eyes of rabbits

9.3.6 Skin Sensitisation (10)

Species/strain:	guinea pig/Hartley Albino
Number of animals:	10 test, 5 control
Test Substance	toner product containing the notified polymer at a concentration of 1 to 5%.
Induction procedure:	
test group: day 1	three pairs of intradermal injections (0.1 mL) into the dorsal skin of the scapular region: - 1:1 v/v Freund's complete adjuvant (FCA) and physiological saline for injection; - 5% w/w of the test substance, in liquid paraffin; - 1:1 v/v mixture of FCA containing the test substance at 10 % w/w and saline v/v,
day 7	a lint cloth wetted with 0.2 mL the test substance, 30% w/w in liquid paraffin was applied to the treated area and held under occlusive dressing for 48 hours
control group:	during the induction phase the control animals were treated similarly to the test animals omitting the test substance from the intradermal injections and topical applications
Challenge procedure:	
day 21	patches wetted with 0.1 mL of 3%, 10% and 30% w/w of test substance in liquid paraffin applied to the shorn flank and held under occlusive dressing for 24 hours
Test method:	OECD TG 406, Magnusson and Kligman Guinea Pig Maximisation Test (3)
Comment:	slight erythema appeared on parts of the skin challenged with the 30% mixtures 3 hours after patch removal and disappeared completely 24 hours later
Result:	the toner product was non sensitising to guinea pig skin

9.2 Genotoxicity

9.2.3 *Salmonella typhimurium* Reverse Mutation Assay (11)

Strains:	TA1535, TA1537, TA1538, TA98, TA100
Test Substance	toner product containing the notified polymer at a concentration of 1 to 5%.
Concentrations:	0, 50, 150, 500, 1 500, 5 000 μg/plate
Metabolic activation system:	liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Test method:	OECD TG 471 (3)
Comment:	no significant increase in the frequency of revertant colonies of bacteria were recorded for any strains of *Salmonella* used, at any dose level in the presence or absence of metabolic activation; no toxicity was observed in any of the strains; precipitation occurred at 1 500 μg/plate and above, however, this did not affect scoring of the revertant colonies positive controls used in the test induced marked increases in the frequency of revertant colonies and the activity of the S9 fraction was found to be satisfactory
Result:	the toner product was not mutagenic under the conditions of study

9.4 Overall Assessment of Toxicological Data

For the notified polymer, assays for mutagenicity were performed in *Samonella typhimurium* and *Escherichia coli* over a concentration range of 156 - 5 000 μg/plate. Negative results were obtained in the presence and absence of metabolic activation. The notified chemical also displayed no clastogenic activity in cultured Chinese hamster cells with or without metabolic activation.

In a 28-day repeat oral dose study in rats (with 14-day recovery), PI-6100 did not exibit any treatment related effects up to 1 000 mg/kg/day.

On the basis of submitted data, the notified polymer would not be classified as hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* (12) with respect to mutagenicity and severe effects after repeated or prolonged exposure.

Studies on the toner product containing the notified polymer (1 to 5%) have been submitted by the second applicant. The test material was of low acute dermal toxicity (LD_{50} > 2 000 mg/kg). The acute inhalation LC_{50} was 5.18 mg/ L /4-hour, which was the mean achieved atmosphere concentration in the study. From the notifiers MSDS, the product toner was of low oral toxicity (LD_{50} >2 000 mg/kg). The test material was non-

irritating and non-sensitising to animal skin. Slight eye irritation, limited to conjunctival effects, was observed in a rabbit study.

The test material did not reveal mutagenic activity in a bacterial mutagenicity assay.

The toner product containing the notified polymer would not be classified a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (13) for the toxicological end points tested.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided, which is acceptable for polymers of NAMW greater than 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.

Hazard from accidental spillage of the polymer should be negligible as it will be marketed in cartridges for direct insertion into photocopier machines.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer will be imported initially as a component (4%) of a electrographic toner and then as a pure chemical. It is not expected to be a health hazard as the NAMW greater than 1 000 should preclude transmission of molecules across biological membranes. Levels of residual monomers and impurities are very low and should not render the polymer a health hazard according to *Approved Criteria for Classifying Hazardous Substances* (12). The level of low molecular weight (< 100) species is also unlikely to render the polymer hazardous.

Toxicological studies show that the notified polymer is not harmful by repeated 28-day oral administration, and is unlikely to be genotoxic.

Acute toxicity data on a toner product containing the notified polymer (<5%) showed low

acute oral toxicity (LD_{50}> 2 000 mg/kg), low dermal (LD_{50} > 2 000 mg/kg) and low inhalation toxicity (LC_{50} > 5 180 mg/m3) in rodents. The product is not a skin irritant in rabbits or a skin sensitiser in guinea pigs but is a slight eye irritant in rabbits.

The product was not considered to show mutagenic activity in a bacterial test system.

The toner product containing the notified polymer would not be classified a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (13) with respect to the toxicological end points tested.

Occupational exposure to the notified polymer in the toner cartridge is expected to be minimal since it is imported in toner cartridges and no repackaging occurs. The only significant occupational exposure expected is when the plastic seal is removed after the cartridge is inserted into the machine. However, as this occurs infrequently, is of short duration and the toner will not be released to the atmosphere, exposure is also expected to be minimal. Exposure during routine machine maintenance is also expected be minimal as a result of containment of the toner containing the notified polymer within the cartridge.

There is little chance of significant exposure to the notified polymer during formulation of toner as it will be carried out in an enclosed system under local exhaust ventilation. It is estimated that only a very small amount of the polymer will be released during formulation (0.009 kg/day). The dust collectors/air filters in the exhaust systems would further limit the release to the atmosphere.

The risk of adverse occupational health effects associated with use of the notified chemical is expected to be low. However, in the event of an accident during transportation or storage, there is a potential for the formation of dust clouds, which may result in a dust explosion.

13. RECOMMENDATIONS

To minimise occupational exposure to PI-6100 the following guidelines and precautions should be observed:

- When changing toner cartridges containing the notified polymer, care should be taken to avoid exposure to the toner adhering to the plastic tape, which seals the cartridge. Should exposure occur, the toner should be removed immediately by washing.

- Good industrial hygiene practices should be implemented during storage and handling.

- Atmospheric dust levels should be kept below 3 mg/m^3 (TWA) in accordance with the Worksafe exposure standards for carbon black (14).

- If engineering controls and/or work practices are insufficient to reduce exposure to the notified polymer to a safe level during toner formulation, the following personal protective equipment should be used:

- Respiratory protection should be chosen according to Australian Standard/New Zealand Standard (AS/NZS) 1715 (15) and Australian Standard (AS) 1716 (16).

- Chemical-type goggles conforming to AS 1336 (17) and AS/NZS 1337 (18).

- Impervious gloves conforming to AS 2161 (19).

- Protective clothing conforming to AS 2919 (20).

- A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (21).

This MSDS was provided by the applicant 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 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. No other specific conditions are prescribed.

16. REFERENCES

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

2. Tennichi M., 1994. *Subacute 28-day oral toxicity (gavage) study with PI-600 in the rat*. Study No: BMR 173C, project on file, Bio-Medical Research Laboratories Co., Ltd, Japan.

3. Organisation for Economic Co-operation and Development, OECD *Guidelines for Testing of chemicals*, OECD, Paris, France

4. Osamu Ueno, 1994, *Salmonella typhimurium and Escherichia coli reverse mutation assay with PI-600*. Study No: 3L372, project on file, General Research Testing Centre, Japan .

5. Osamu Ueno, 1994, *Chromosome aberration assay in Chinese hamster Mamalian cells in vitro with PI-600*. Study No: 3L373, project on file, General Testing Research Cente, Japan.

6. Sanders A (1997). N26T: Acute Dermal Toxicity in the Rat. Derby, Safepharm Laboratories Limited.

7. Blagden SM (1996). N26T: Acute Inhalation Toxicity (Nose Only) Study in the Rat. Derby, Safepharm Laboratories Limited.

8. Sanders A (1997). N26T: Acute Dermal Irritation in the Rabbit. Derby, Safepharm Laboratories Limited.

9. Sanders A (1997). N26T: Acute Eye Irritation Test in the Rabbit. Derby, Safepharm Laboratories Limited.

10. Iihama K (1997). The Delayed Contact Hypersensitivity Study of N26Tc in Guinea Pigs Maximization Test. Saitama, Drug Safety Testing Center Co. Ltd, Saitama Institute.

11. Thompson PW (1997). N26T: Reverse Mutation Assay "Ames Test" Using *Salmonella typhimurium*. Derby, Safepharm Laboratories Limited.

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

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

14. 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*

15. 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.

16. Standards Australia, Standards New Zealand, 1991. *Australian/New Zealand Standard 1716 - 1991 Respiratory Protective Devices,* Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ., Wellington, New Zealand.

17. Australian Standard 1336-1982, *Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, 1982.

18. Australian Standard 1337-1984. *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, 1984.

19. Australian Standard 2161-1978. *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.

20. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.

21. National Occupational Health and Safety Commission (1994). *National Code of Practice for the Completion of a 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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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