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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Lexmark acrylic terpolymer

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For enquiries please contact the Administration Section at:

Street Address: 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA
Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

TABLE OF CONTENTS

FULL PUBLIC REPORT

Lexmark acrylic terpolymer

1. APPLICANT

Lexmark International Inc. of 12A Rodborough Rd, Frenches Forest NSW 2086 has submitted a limited notification statement in support of their application for an assessment certificate for **Lexmark acrylic terpolymer**.

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 and the Summary Report.

Marketing Name: Lexmark acrylic terpolymer

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Off-white crystalline solid
Melting Point:	252°C (with decomposition)
Relative Density:	1.30 at 22°C
Vapour Pressure:	7.9×10^{-5} Pa at 25°C
Water Solubility:	> 156 g/L at 20°C
Surface Tension	66.8mN/m at 19 ± 0.5°C (for a 1.11 g/L solution)
Partition Co-efficient (n-octanol/water):	$Log_{10} P_{ow} = -2.92$
Hydrolysis as a Function of pH (at 25°C):	$T_{1/2}$ at pH 4, 7, 9 > 1year
Adsorption/Desorption:	$Log_{10} K_{oc} < 1.34$
Dissociation Constant:	Not determined – see notes
Particle Size Distribution:	> 100 μm

Flash Point:	Not conducted
Flammability Limits:	Not highly flammable (Method A10 Commission Directive 92/69/EEC.
Autoignition Temperature:	311°C
Explosive Properties:	Non explosive
Reactivity/Stability:	Non oxidising

3.1 Comments on Physico-Chemical Properties

The vapour pressure (VP) of the notified polymer was determined using a vapour pressure balance system. Determination involved measuring the change in mass of the notified polymer when placed under a vacuum and subject to temperatures between 200 and 220ºC. Three series of mass difference readings were taken at time intervals beginning at 1½ hours after heating, then at 15¼ and 20¾ hours, respectively. A regression slope calculated using measurements taken during run 3 (at 220ºC) was used to extrapolate the VP value to 25ºC (SafePharm, 1997d). The VP value indicates the polymer is not volatile at 25ºC.

The water solubility of the notified polymer was determined using the flask method (Method A6 Commission Directive 92/69/EEC). The method involved dissolving 3 samples containing approximately 5, 10 and 15 grams of the test material in 100 mL distilled water, and 3 samples containing approximately 10, 13 and 15 grams of the test material in 50 mL distilled water. The samples groups were shaken for periods of 231¼ hours and 40 hours. After a 24 hour settling period, the extent of dissolution was assessed visually. An aliquot of the sample containing 150 g/kg water was analysed for absorbance at 195 nm in cells of 10 mm path length using distilled water as a reference medium (SafePharm, 1996a). At concentrations greater than 150 g/kg of water, the solutions formed a viscous paste, and as more material was added, it formed a solid mass. The viscous solutions contained significant quantities of undissolved material.

The surface tension of the notified polymer was determined by the ring method (OECD TG 115) using an interfacial tension balance. The surface tension of a 1.11g/L solution of the polymer was found to be 66.8mN/m at 19 ± 0.5°C, and hence the substance is not regarded as surface active (ie. < 60 mN/m) (SafePharm, 1997e).

The partition coefficient was determined using the Shake Flask Method (Method A8 Commission Directive 92/69/EEC). The stock partitioning mixture was prepared using 1.0 g/L of substance in n-octanol saturated water. Three sets of duplicate samples were prepared containing ratios of 8:1, 4:1, and 2:1 octanol saturated water to stock solution respectively. Vials were mixed for 5 minutes until phase separation occurred. The concentration of the notified polymer in each phase was calculated using ICPMS to determine the concentration of silicon and then converting to equivalents of test material (SafePharm, 1996a). The P_{ow} was determined to be 1.2×10^{-3} indicating the polymer has a relatively poor affinity to lipids (van Leeuwen and Hermens, 1995).

A preliminary Hydrolysis as a Function of pH Test was performed at a temperature of 50°C

for a period of 5 days at pH values of 4, 7 and 9 to test the abiotic degradation of the notified polymer (OECD TG 111). No measurable hydrolysis took place over the 5 day test period at any test pH value indicating the polymer is hydrolytically stable. The polymer was assigned an estimated half-life of >1 year at 25°C (SafePharm, 1997e).

The soil adsorption coefficient (Koc) of the notified polymer was determined using an HPLC screening method outlined in a draft "HPLC-screening method for the determination of the adsorption-coefficient on soil-comparison of different stationary phases". The method has not been validated for use with polymers, but is routinely used with pesticides and other organic compounds. According to the report provided in the dossier, the OECD Method 106 was unsuitable because the changes in concentrations due to adsorption were too low for accurate detection at the working level used (ie. 5 mg/L). It was also thought that the solubility of the polymer would be severely impaired in the presence of calcium chloride, which is used as an aqueous solvent phase in the OECD method (Safepharm, 1997e).

The HPLC-screening method involved passing the notified polymer, dissolved in an aqueous medium, through an HPLC column and determining the retention times. The capacity factor and $\log_{10}K_{oc}$ value were determined with reference to a calibration curve constructed using formamide to establish dead time, and a suite of 10 reference standards to determine retention times (Safepharm, 1997e). The Koc (organic carbon normalised adsorption coefficient) was determined to be <21.9.

According to the notifier, determination of the dissociation constant is inappropriate given the structure and the physicochemical properties of the polymer.

4. PURITY OF THE CHEMICAL

Degree of Purity:	98.3-99.2 %
Hazardous Impurities:	None
Non-hazardous Impurities (> 1% by weight):	None
Additives/Adjuvants:	None

5. USE, VOLUME AND FORMULATION

The specific use and manufacture/import volumes have been exempted from publication in the Full Public Report and the Summary Report.

The notified polymer (at a maximum concentration of 2%) is to be used in aqueous ink formulations. The notifier plans to import less than five tonnes per year of notified chemical.

6. OCCUPATIONAL EXPOSURE

Printing inks containing the notified polymer will be imported in pre-packed cartridges, each

containing a maximum of 2 % w/w notified polymer.

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached.

Office workers may be exposed via the dermal route to the notified polymer contained in the ink cartridge when replacing the spent ink cartridge. Exposure is expected to be controlled through the design of the ink cartridges and the printing machines. Pre-packed ink cartridges are sealed and worker exposure to the ink is minimised by the use of the replacement procedures recommended by the manufacturer.

Maintenance workers for printers may potentially come in contact with the notified polymer more often than office workers. Printer maintenance workers may be exposed via dermal and inhalation routes to the notified polymer contained in the ink cartridge during repair maintenance and cleaning of ink jet printers. Printer maintenance personnel often wear cotton disposable gloves to limit dermal exposures. Respiratory exposure of printer maintenance workers to airborne particles is low, as the particle size distribution of the notified polymer is greater than 100 μm, indicating that any inhaled particles are unlikely to deposited.

Contact with paper printed with printing inks containing the notified polymer is unlikely to result in dermal exposure, as it will be bound in the structure of the paper.

7. PUBLIC EXPOSURE

The ink is contained in the cartridge and the physical design of the cartridge prevents handlers from accidentally touching the ink. The design also prevents leakage of ink. The loading and removal of a cartridge into or from its containment area in a printer can be readily accomplished without any contact with ink. Malfunctioning or empty cartridges are replaced with new ones. No attempt is made to repair or fill them with ink again.

Members of the public may be exposed to the notified polymer via dermal contact in attempts to insert or remove a damaged cartridge or to remove a paper jam. Such contact will be infrequent and transient. On printed paper on which the ink has dried, the notifiable polymer is not likely to transfer to human skin. Therefore, the proposed use of the notified polymer offers little opportunity for public exposure.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Transport, Insertion and Disposal of Cartridges

Losses of the notified polymer during transport to sites of sale are not expected because the chemical is housed in sealed cartridges. These cartridges are designed to prevent release of the ink until the sealing tape is removed and the cartridges are inserted into an inkjet printer. Incidental losses during insertion of the cartridge and normal use of a printer are also not expected. In the event of accidental spills either during transport or cartridge insertion, it is expected that the ink wastes will be collected and sent to either landfill or incineration.

Some release of the notified polymer is anticipated following disposal of the spent ink cartridges. The notifier estimates up to 10% of ink, containing 1.5% of notified polymer, may remain in spent cartridges. Most spent cartridges are likely to be sent to landfill. As such, about 3.75 kg of the notified polymer may enter the environment each year at landfill sites. Due to the anticipated nationwide use, the disposal would be widespread across Australia.

Recycling of Printed Paper

Most of the notified polymer will be deposited with the ink blend onto sheets of paper during the printing process. The waste paper generated will eventually be disposed of either through recycling, landfill or incineration.

Paper recycling is carried out in paper mills, where it is likely that at least primary sedimentation occurs, with some facilities also having biological treatment facilities. During the recycling process, waste paper is repulped using a variety of alkalis, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from paper fibres, pulp brightness, and the whiteness of paper (EC, 1994).

It is estimated that the removal rate of ink particles from paper during the de-inking phase of recycling is 30-60% efficient for inkjet copying (EC, 1994). These inks are expected to reside in the sewerage system and may eventually be released into the local sewage treatment works with the effluent water after treatment. The insoluble substances retained in the paper fibre or in the sludge will eventually be used to make recycled paper, or will be disposed to landfill with waste sludge (EC, 1994). As such, up to 60 % of the notified polymer contained in the ink blend could enter the aquatic compartment via sewage treatment facilities, with the remainder eventually being sent to landfill.

8.2 Fate

Because the notified polymer will be bound to printed paper, its fate will be dictated by paper disposal and recycling trends. Recent literature suggests that current paper recycling rates in Australia are 70-92% (Australian Environmental Review, 2001). During de-inking up to 60% of the total import volume could reside in the sewerage system, where it may associate with the aquatic compartment.

The results of a Ready Biodegradability CO_2 Evolution Test (OECD TG 301B) indicate the notified chemical is not readily biodegraded under aerobic conditions. Only 4% of the test substance, representing 20 mgC/L of notified polymer, was degraded at the end of the 28-day test period when incubated in a culture containing microorganisms in activated sewage sludge. This compared to 100% of the reference substance, sodium benzoate, degraded after 8 days, indicating the inoculum was viable. A toxicity control containing the notified substance and the sodium benzoate attained 54% degradation after 28 days indicating that the test material was not toxic to the microorganisms in the sewage sludge (SafePharm, 1996b). Hence, in industrial effluent and sewage treatment facilities, the polymer is not expected to be eliminated by microorganisms, but to remain in the aquatic compartment from where it will eventually be released into natural waterways.

The remaining 40% of the notified polymer residing in solid wastes generated from the recycling process will become an integral part of recycled paper or will be disposed of with solid wastes. Most solid wastes are either incinerated or sent to landfill.

Incineration of the notified polymer is expected to destroy the polymer and result in the release of combustion products such as carbon monoxide, carbon dioxide, organic acids and unidentified low molecular weight organics. Any polymer sent to landfill, either fixed to paper, residing in sludge, or released from ruptured cartridges, could potentially enter the aquatic compartment via surface runoff or percolating groundwater. McCall *et al*. (1980) have developed a soil mobility classification based on K_{oc} values determined using HPLC retention times and correlated to leaching distances in soils. The K_{oc} value of the notified polymer measured using HPLC indicates it will not adsorb onto organic matter but will be highly mobile in soils.

It is stated in the notification dossier that the substance is ionisable. As such under suitable conditions of pH, the potassium salt on the polymer chain could form a precipitate with ionic substances residing in soil water solutions, in paper recycling facilities, or in the sewage treatment plant. Precipitation in the treatment facilities would lead to its removal with the solid waste sludges. Precipitation in the soil water solution would retain the polymer in the upper soil horizons where it would be expected to undergo slow degradation by biotic and abiotic processes, unless conditions change and the substance is remobilised.

No bioaccumulation test was carried out for the notified polymer. However, the polymer's high molecular weight (>3000) would preclude any appreciable absorption across biological membrane. Hence the substance is not expected to bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Lexmark acrylic terpolymer

Test	*Species*	*Outcome*	Reference
Acute oral toxicity	rat	LD50 > 5000 mg/kg bw	Corning Hazleton Inc. 1995
Acute dermal toxicity	rat	LD50 > 2000 mg/kg bw	Safepharm Laboratories Limited 1997
Skin irritation	rabbit	Non-irritant	Corning Hazleton Inc. 1995a
Eye irritation	rabbit	Slight to moderate irritant	Corning Hazleton Inc. 1995b
Skin sensitisation	guinea pig	Non sensitiser	Corning Hazleton Inc. 1995c
			Safepharm Laboratories Limited 1996

9.1.1 Oral Toxicity (Corning Hazeton Inc. 1995)

Species/strain:	Albino rat of the Crl:CD(SD)BR strain
Number/sex of animals:	Five male and five female rats per dose
Observation period:	14 days
Method of administration:	Single oral (gavage) dose at 5 000 mg/kg bw
Test method:	US EPA Guidelines and OECD TG 401
Mortality:	No mortality was observed at 5 000 mg/kg bw
Clinical observations:	All rats gained weight during the study. 1/5 female rat exhibited hypoactivity on the day of treatment. 1/5 female rat exhibited red stained face on the day of treatment.
Morphological findings:	No lesions were observed at necropsy.
LD_{50}:	> 5 000 mg/kg bw
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Safepharm Laboratories Limited 1997)

Species/strain:	Sprague-Dawley CD rat
Number/sex of animals:	Five male and five female rats per dose
Observation period:	14 days
Method of administration:	A single, 24 hour semi-occluded application to intact skin at 2 000 mg/kg bw.
Test method:	OECD TG 402
Mortality:	No mortality was observed at 2 000 mg/kg bw
Clinical observations:	All rats gained weight during the study. No signs of systemic toxicity were noted.
Morphological findings:	No abnormalities were noted at necropsy.

Draize scores:

Time after treatment (days)	**Animal #**									
	Male rats					***Female rats***				
	1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***
Erythema	[i]									
1	0	0	1	1	0	1	1	0	1	0
3	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0
Oedema										
1	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0

[i] see Attachment 1 for Draize scales

LD_{50}: > 2 000 mg/kg bw

Result: The notified chemical was of very low dermal toxicity in rats

9.1.3 Inhalation Toxicity

Variation to the schedule of data requirements is claimed.

9.1.4 Skin Irritation (Corning Hazleton Inc. 1995a)

Species/strain: Albino Hra: (NZW) SPF rabbit

Number/sex of animals: Three male and three female rabbits

Observation period: 3 days

Method of administration: A semi-occluded application of 0.5 g of neat test material in 1 mL distilled water to intact skin. After 4 hours the substance was removed with tap water.

Test method: US EPA Guidelines and OECD TG 404

Comment: In one animal the test material resulted in a very slight erythema reaction that cleared within 24 hours. All other Draize scores were zero.

Result: The notified chemical was not irritating to the skin of rabbits.

9.1.5 Eye Irritation (Corning Hazleton Inc. 1995b)

Species/strain: Albino Hra: (NZW) SPF rabbit

Number/sex of animals: Six rabbits

Observation period: 7 days

Method of administration: A single 0.1 mL (68 mg test material) was applied to the everted lower lid of the right eye.

Test method: US EPA Guidelines and OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation									
Animal	***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***	***o***	***a***
1	1[1]	1	1	1	0	0	0	0	0	0
2	1	1	1	1	0	0	0	0	0	0
3	1	1	0	0	0	0	0	0	0	0
4	1	1	1	1	1	1	0	0	0	0
5	1	1	0	0	0	0	0	0	0	0
6	1	1	0	0	0	0	0	0	0	0
Iris										
1	1		0		0		0		0	
2	0		0		0		0		0	
3	0		0		0		0		0	
4	1		0		0		0		0	
5	0		0		0		0		0	
6	0		0		0		0		0	
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	2	1	2	1	0	2	1	0	2	1	0	0	0	0
2	2	1	0	2	1	0	2	1	0	1	1	0	0	0	0
3	2	1	1	2	1	0	1	0	0	0	0	0	0	0	0
4	2	2	1	2	1	0	2	1	0	2	1	0	0	0	0
5	2	1	0	2	1	0	2	0	0	1	0	0	0	0	0
6	2	1	0	1	1	0	1	1	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: The test material produced corneal and iridal involvement

and moderate conjunctival irritation. All treated eyes had returned to a normal appearance by day 7 after treatment.

Result: The notified chemical was slight to moderately irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Corning Hazleton Inc. 1995c)

Species/strain: Albino Crl:(HA)BR guinea pig

Number of animals: Irritation screening group: 4 animals
Treatment group: 10 animals
Control group: 4 animals

Irritation screening: The test material at concentrations of 1%, 10%, 15%, and 25% in petrolatum was applied in a thick even layer to 2 cm x 2 cm Whatman No. 3 filter papers, applied to two sites on the shaved back of each animal, covered with overlapping strips of Blenderm^{TM} tape and overwrapped with Elastoplast^{R} tape. Each animal received two different concentrations of the test material. The patches were removed after 24 hours. Examinations for dermal irritation (erythema and oedema) were made 24 and 48 hours after patch removal.

Induction procedure:

Test group:

Day 1 Three pairs of intradermal injections, of 0.05 mL volume, were made in the scapular region (2 cm x 4 cm shaved area):

- FCA diluted 1:1 with sterile water
- 5% w/v test material in sterile water
- 5% w/v test material in 1:1 FCA and sterile water

Day 7 10% w/w sodium lauryl sulphate (SLS) in petrolatum applied topically with a glass rod. The solution was applied uniformly over the area that received the dermal injections on day 1. No bandage was applied.

Day 8 0.5 mL of 25% w/w test material in petrolatum was applied in a thick even layer to 2 cm x 4 cm Whatman No. 3 filter papers and placed over the injection sites. These were covered with overlapping strips of Blenderm^{TM} tape and overwrapped with Elastoplast^{R} tape. The patches were removed after 48 hours.

Control group:

Day 1 Three pairs of intradermal injections, of 0.05 mL volume, were made in the scapular region (2 cm x 4 cm shaved area):

- FCA diluted 1:1 with sterile water
- Sterile water
- 1:1 FCA and sterile water

Day 7 10% w/w sodium lauryl sulphate (SLS) in petrolatum applied topically with a glass rod. The solution was applied

	uniformly over the area that received the dermal injections on day 1. No bandage was applied.
Day 8	0.5 mL of petrolatum was applied in a thick even layer to 2 cm x 4 cm Whatman No. 3 filter papers and placed over the injection sites. These were covered with overlapping strips of Blenderm^{TM} tape and overwrapped with Elastoplast^{R} tape. The patches were removed after 48 hours.

Challenge procedure:

Day 22	25% w/w test material in petrolatum and petrolatum alone were applied in a thick even layer to 2 cm x 2 cm Whatman No. 3 filter papers. The filter paper containing the test material was placed over half of the sites that received an intradermal injection on day 1. The filter paper containing petrolatum was placed over the remaining three intradermal injection sites. The patches were sealed under strips of Blenderm^{TM} tape for 24 hours with complete occlusion made by overwrapping of Elastoplast^{R} tape around the trunk.

Test method: US EPA Guidelines

Irritation screening outcome:

The test material did not cause dermal irritation at the doses tested.

Challenge outcome:

	Test animals		Control animals	
Challenge concentration	**24 hours***	**48 hours***	**24 hours**	**48 hours**
25%	0/9**	0/9	0/4	0/4

* time after patch removal
** number of animals exhibiting positive response

Comment: No irritation observed in test animals during the induction phase. 1/10 animals in the treatment group exhibited a thin appearance and hypoactivity on day 10 and was found dead on day 11. Weight losses of 5-29 g were noted in 3/9 animals in the test group and 2/4 animals in the control group during the last 4 days of the study.

Result: The notified chemical was not sensitising to the skin of guinea pigs.

9.1.7 Skin Sensitisation (Safepharm Laboratories Limited 1996)

Species/strain: Albino Dunkin Hartley guinea pig

Number of animals: Irritation screening: 2 animals per study
Treatment group: 10 female animals

Control group: 5 female animals

Irritation screening:

Intradermal application: Two animals received four intradermal injections of 0.1 mL of the test material in distilled water. One animal received 1% test material and the other 5% test material. The degree of erythema at the injection sites was assessed 24, 48 and 72 hours and 7 days post injection according to the Draize scale.

Topical application: Two animals that had been pre-treated intradermally with FCA nine days earlier, received a topical application with 5%, 10%, 25% and 50% test material in distilled water to shaved skin under occlusion for 48 hours. The degree of erythema and oedema was assessed 1, 24, and 48 hours after dressing removal.

Induction procedure:

Test group:

Day 0: Three pairs of intradermal injections, of 0.1 mL volume, were made in the scapular region:

- FCA diluted 1:1 with distilled water
- 1 % w/v test material in distilled water
- 1 % w/v test material in 1:1 FCA and distilled water

Day 7: 50% w/w test material in distilled water was applied in a thick even layer to 2 cm x 4 cm Whatman No. 4 filter papers and placed over the injection sites. These were covered with Blenderm^{TM} tape and covered with an overlapping length of aluminium foil. The patch and foil were secured with Elastoplast^{R} tape. The occlusive dressing was held in place for 48 hours.

Control group:

Day 1: Three pairs of intradermal injections, of 0.1 mL volume, were made in the scapular region:

- FCA diluted 1:1 with distilled water
- Distilled water
- 50% w/v FCA in 1:1 FCA and distilled water

Day 7: Distilled water was applied in a thick even layer to 2 cm x 4 cm Whatman No. 4 filter papers and placed over the injection sites. These were covered with Blenderm^{TM} tape and covered with an overlapping length of aluminium foil. The patch and foil were secured with Elastoplast^{R} tape. The occlusive dressing was held in place for 48 hours.

Challenge procedure:

Day 21: Whatman No. 4 filter papers (2 cm x 2 cm) saturated with 5% w/w test material in distilled water were placed over half of the sites on each animal that received intradermal injections on day 1. Whatman No. 4 filter papers saturated with 2% w/w test material in distilled water were placed over the remaining three intradermal injection sites. The

patches were held in place with strips of Blenderm™ tape for 24 hours.

Test method: OECD TG 406

Irritation screening outcomes:

Intradermal application: 5% test material in distilled water caused moderate to severe erythema that had not resolved by day 7.

Topical application: 50% test material in distilled water caused mild erythema that had resolved within 48 hours.

Challenge outcome:

	Test animals		Control animals	
Challenge concentration	**24 hours***	**48 hours***	**24 hours**	**48 hours**
2%	0/10**	0/10	0/5	0/5
5%	0/10	0/10	0/5	0/5

* time after patch removal
** number of animals exhibiting positive response

Comment: Slight to well-defined erythema was noted at the intradermal induction sites of all test group animals at 24 and 48 hour post administration. Slight erythema was noted in 3/5 animals in the control group 48 hours post injection.

Slight to well-defined erythema, with or without slight oedema, was noted at the topical induction sites of all test group animals 1 hour post administration. Slight erythema was noted in 6/10 animals in the control group 24 hours post application. No skin reactions were noted in the control group 1 and 24 hours post application.

Between day 0 and 24 of the main study the body weight gain of animals in the test group was similar to that of controls.

Result: The notified chemical was not sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Safepharm Laboratories Limited 1997a)

Species/strain: Sprague-Dawley Crl:CD/BR rats.

Number/sex of animals: Five/sex/group.

Method of administration: Oral (gavage).

Dose/Study duration: 0, 150, 400 and 1000 mg/kg bw/day for 28 days.

Test method: Commission Directive 92/69/EEC (Method B7). Similar to OECD TG 407.

Clinical observations:
No mortality was observed during the study. No clinically observable signs of toxicity were detected in test or control animals throughout the study. No obvious treatment related effects were seen in body weight gain, food consumption or water consumption.

Clinical chemistry/Haematology
No obvious dose related treatment effects were seen on haematological indices or clinical chemistry.

A statistically significant reduction ($p<0.05$) in group mean clotting time was detected in males treated with 1000 mg/kg bw/day when compared to controls, however, all values were within the normally expected rats of the strain and age used.

A statistically significant increase ($p<0.001$) in group mean plasma potassium concentration was detected in males treated with 1000 mg/kg bw/day when compared to controls. A statistically significant reduction ($p<0.05$) in group plasma urea and sodium concentrations were detected in females treated with 1000 mg/kg bw/day when compared to controls. These changes in blood chemistry parameters were minor and, in the absence of supportive data, considered not significant toxicologically.

Pathology:
No statistically significant treatment related macroscopic lesions or dose related effects on organ weight were noted.

At necropsy, 1/5 males that received 400 mg/kg bw/day showed hydronephrosis of the right kidney and both kidneys of 2/5 animals that received 1000 mg/kg bw/day had a speckled appearance. No differences were reported for males in the control group and those that received 150 mg/kg bw/day. All females were normal.

A statistically significant reduction in group adrenal weight, both absolute and relative to bodyweight, was detected in males treated with 400 ($p<0.01$) and 1000 ($p<0.05$) mg/kg bw/day when compared to controls. The relative adrenal weight was also reduced in males at 150 mg/kg bw/day. As the effect was not dose related and no histological changes were detected supporting an adverse adrenal effect, the reduction in group adrenal weight was not considered toxicologically relevant.

A statistically significant increase ($p<0.05$) in group mean gonad and heart weight were detected in males treated with 400 and 1000 mg/kg bw/day respectively when compared to controls. A statistically significant increase ($p<0.05$) in group heart weight were also detected in females treated with 400 mg/kg bw/day.

A statistically significant increase ($p<0.05$) in group mean kidney weight was detected in females treated with 400 and 1000 mg/kg bw/day respectively when compared to controls.

Histopathology:
No statistically significant treatment related microscopic lesions were noted.

Comment:
No statistically significant adverse dose related treatment effects were reported.

Result:
In the absence of adverse health effects, the no observed adverse effect level (NOAEL) is determined to be 1000 mg/kg bw/day, the highest dose tested.

9.3 Genotoxicity

9.3.1 *Escherichia coli* Reverse Mutation Assay (Safepharm Laboratories Limited 1997b)

Strains:	*Escherichia coli:* WP2uvrA
Metabolic activation:	Liver S9 fraction from rats induced with Aroclor 1254
Concentration range:	0, 50, 150, 500, 1500, and 5 000 μg/plate of test substance. Each concentration was tested in triplicate with or without metabolic activation. Strain specific positive control reference substances were used.
Test method:	Similar to OECD TG 472
Comment:	Precipitation was observed at and above 1500 μg/plate. Toxicity characterised by growth inhibition was not observed at any dose tested. No significant increase in the number of revertant colonies above the negative control was detected. Concurrent 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 notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in vitro (Safepharm Laboratories Limited 1997c)

Cells:	Human peripheral blood lymphocytes
Metabolic activation system:	Liver fraction (S9) from rats pretreated with Aroclor 1254
Dosing schedule:	

Metabolic Activation	Experiment Number	Test concentration (μg/mL)	Controls
-S9	1	Treatment time = 20 hours. Test concentration = 0*, 39, 78.1, 156.25, 312.5, 625*, 1250*, 2500* and 5000* microgram/mL.	Positive: EMS Negative: Vehicle = minimal essential medium
	2	Treatment time = 20 hours. Test concentration = 0*, 1250*, 2500*, 3750* and 5000 microgram/mL.	
	2	Treatment time = 44 hours. Test concentration = 0*, 1250, 2500*, 3750 and 5000 microgram/mL.	
+S9	1 (S9 = 1%)	Treatment time = 4 hours; expression time = 16 hours. Test concentration = 0*, 39, 78.1, 156.25, 312.5, 625, 1250*, 2500* and 5000* microgram/mL.	Positive: CP Negative: Vehicle = minimal essential medium
	2 (S9 = 1%)	Treatment time = 4 hours; expression time = 16 hours. Test concentration = 0*, 1250, 2500*, 3750* and 5000* microgram/mL.	
	2 (S9 = 1%)	Treatment time = 4 hours; expression time = 40 hours. Test concentration = 0*, 1250, 2500, 3750 and 5000* microgram/mL.	

EMS - ethyl methanesulphonate
CP - cyclophosphamide
DMSO – dimethylsulphoxide
* - cultures selected for metaphase analysis

Test method: OECD TG 473

Comment: Positive controls demonstrated the sensitivity of the test and negative controls were within historical limits.
No precipitation was observed.
In both experiments 1 and 2 a consistent reduction in mitosis was observed in the 20-hour study at 2500 μg/mL (29%) and above when cultured in the absence of metabolic activator. In experiment 2 a consistent reduction in mitosis was observed in the 20-hour study at 5000 μg/mL (46%) when cultured in the presence of metabolic activator.
In experiment 1 a reduction in mitosis was observed in the 44-hour study at 2500 (61%) and 3750 μg/mL (74%) when cultured in the absence of metabolic activator and at 5000 μg/mL (59%) when cultured in the presence of metabolic activator. This effect was not reproduced in experiment 2.
A statistically significant increase in the frequency of cells with aberrations was observed in the 20-hour study at 5000 μg/mL ($p<0.01$) when cultured in the absence of metabolic activator. The aberrations observed were primarily

	chromatid gaps or breaks. No chromatid exchange aberrations were detected. However at this dose the level of toxicity was close to the maximum acceptable limit. A small but statistically significant increase in the frequency of cells with aberrations was observed in the 44-hour study at 5000 μg/mL ($p<0.05$) when cultured in the presence of metabolic activator. However this score was within the acceptable range for vehicle controls. The test material did not induce a significant increase in the numbers of polyploid cells.
Result:	The notified chemical was non clastogenic under the conditions of the test.

9.3.3 Induction of germ cell damage

Variation to the schedule of data requirements is claimed.

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity and low acute dermal toxicity in rats (each LD50 > 2000 mg/kg). It was not a skin irritant in rabbits, but a slight to moderate eye irritant. It was not a skin sensitiser in two guinea pig maximisation studies.

No significant systemic toxicity was observed in a 28-day oral repeated dose study in rats (NOAEL = 1000 mg/kg/day). Minor changes in organ weight and blood chemistry parameters were observed, however, in the absence of supporting histopathological evidence, the changes were not regarded as toxicologically significant.

Neither mutagenicity in bacteria nor clastogenicity in human lymphocytes was observed in respective in vitro assays.

The notified chemical is not determined to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided ecotoxicity studies for fish, Daphnia, and algae. The test results for fish and algae are summarised in the table below. Unless otherwise recorded, all tests were performed according to OECD/EEC Test Methods and in compliance with OECD Principles of Good Laboratory Practice.

Test	*Species*	*Results*
Acute Toxicity to fish (OECD TG 203)	Rainbow Trout *Oncorhynchus mykiss*	96 h LC_{50} > 100 mg/L NOEC = 100 mg/L

Algal Growth Inhibition Test (OECD TG 201)	Green Algae *Scenedesmus subspicatus*	72 h E_bC_{50} > 100 mg/L 72 h E_rC_{50} > 100 mg/L $NOEC_b$ = 100 mg/L $NOEC_r$ = 100 mg/L

* NOEC - no observable effect concentration

Acute Toxicity to Fish

An acute toxicity test was conducted to determine the effects of the notified polymer on fish. To select appropriate test concentrations, a preliminary rangefinding test was carried out over 96 hours against 3 fish (per concentration) using nominal test concentrations of 1, 10 and 100 mg/L of the test substance. No fish mortalities were observed during the test using these concentrations (SafePharm, 1997f). Following the rangefinding test, a definitive semi-static test was performed over a period of 96 hours on 2 groups of 10 juvenile rainbow trout using nominal concentrations of 0 (control) and 100 mg/L of the notified polymer. No fish mortalities were observed during the definitive test.

The stock solution used to prepare the test concentrations was made by dispersing 10 g of the test substance (a white crystalline solid) using ultrasonification (45 minutes) in purified reverse osmosis water, adjusted to give a concentration of 2 g/L. An aliquot of the stock solution was then added to carbon filtered, dechlorinated tap water, softened to give a total hardness of approximately 100 mg/L $CaCO_3$, to make up the required concentration. The concentrations of the notified polymer in the stock solution and in the test samples were verified using GPC at 0, 24, and 72 hours.

Preliminary tests showed that when the test substance was added to purified water, it was observed to be soluble. However, when it was added directly to de-chlorinated tap water, it reacted instantaneously to form an insoluble precipitate, which formed a stable dispersion throughout the exposure period.

During GPC analysis conducted to verify test concentrations, a lower molecular weight impurity comprising 10% of the test material was detected. Upon formation of the precipitate, there was no decrease in the concentration of the impurity, indicating that the impurity was stable in tap water. By comparison, the measured concentrations of the main component in the test substance ranged from less than the limit of quantification to 42% of nominal. It was suggested that the carboxylic acid potassium salt in the notified polymer reacted with alkali earth metals present in the medium, producing insoluble calcium and magnesium salts of the test material.

Estimation of LC_{50} values were based on nominal test concentrations of the test material rather than on measured concentrations, because it was not possible to attribute the toxicity of the test material to the main component or to the impurity.

Algal Inhibition Test

An Algal Growth Inhibition test was performed to assess the effects of the notified polymer on the growth of the green algae, *Scenedesmus subspicatus*. To determine appropriate test concentrations, a rangefinding test was conducted against green algae over a period of 72

hours, using nominal test concentrations of 0 (control), 0.1, 1.0, 10 and 100 mg/L of test material.

Preliminary tests showed that when the test substance was added to purified water, it was observed to be soluble, however, when the test substance was added directly to de-chlorinated tap water, it reacted instantaneously to form an insoluble precipitate, which formed a stable dispersion throughout the exposure period. Consequently, the test media were made up by taking aliquots from an aqueous stock solution, which was prepared by dispersing enough test substance in purified reverse osmosis water to give a concentration of 2000 mg/L. The aliquots of stock solution were mixed with the algal suspension to give the required test concentrations. No effects on the growth rate or biomass of algae were observed at any of the test concentration used during the rangefinding test (SafePharm, 1997g).

Following the rangefinding test, a definitive test was performed over a period of 72 hours against green algae containing nominal cell densities of 10^4 cells/mL and using nominal concentrations of 0 (control) and 100 mg/L of the notified chemical. Test temperatures were maintained at 24°C and illumination intensities at 7000 lux. Increases in pH values over the test period did not exceed 0.4 pH units (ie. 7.3-7.7). The test concentrations were verified at 0 and 72 hours by GPC analysis of the control and pooled test samples (R1-R3 and R4-R6). The algal growth rate and the algal biomass were not affected by the presence of the test material over the 72-hour exposure period.

Measured concentrations of the test material at the start of the test were between 69 and 81% of nominal, and the measured concentration of the impurity was near nominal. However, measured concentrations of the test material after 72 hours showed a marked decline to between 13 and 26% of nominal, and the impurity to less than the limit of quantification. The decline in the concentrations of the main component in the test medium over the test period was attributed to the formation of a precipitate. The decline in the concentration of the impurity was probably due to its inherent instability, which was evident after storage under both light and dark conditions.

The estimated EC_{50} and NOEC were determined to be ≥ 100 mg/L. These estimates are based on nominal test concentrations rather than on measured concentrations of the test substance. The use of nominal concentration to express exposure values was justified because the test substance contained an impurity, and the concentration of test substance was observed to decline over the test period.

Acute Toxicity to Daphnia

An acute toxicity to *Daphnia* test, performed using the analogue Lexmark Acrylic Copolymer was provided by the notifier as a proxy test for the acute toxicity to *Daphnia*. The test media were prepared by mixing the test material, a poorly soluble white crystalline solid, into water and stirring for 24 hours using a magnetic stirrer. The solid phase was then separated by filtration and the organisms exposed to the water-soluble fraction (WSF), deemed to be the equivalent of 2.02 mg of test material/L (SafePharm, 1996c).

The *Daphnia* test results have not been included in the summary table because of the different test substance used. In addition, the *Daphnia* test was performed using test media containing the filtered, water-soluble fraction, rather than the entire test substance. There were also some apparent differences in solubility between the notified polymer and the

surrogate test substance. For example, the surrogate substance was reported to be insoluble in water, however, there is no mention of it forming a precipitate when added to de-chlorinated water. The hardness of the water used during the Daphnia test was also higher (270 mg/L $CaCO_3$) than used in the fish test 100 mg/L $CaCO_3$ which could have influenced precipitation.

Some differences in the final measured concentrations of dissolved test substance in the test media may also be attributed to the differing methods used to verify concentrations. The concentration of the surrogate test substance in the test medium was verified at 0 and 48 hours, by determining the silicon content using ICPMS. The mean concentration of silicon in the test solution at 0 hours was less than the concentration in the control. This was attributed to analytical variation resulting from the low levels of silicon in the test samples. The mean concentration after 48 hours, using a nominal loading rate of 100 mg/L, was 0.15 mg Si/L (corrected for the control), or the equivalent of 2.02 mg of test material/L. By comparison the concentration of the notified substance in the test media after 48 hours was measured directly using GPC. The mean concentrations ranged from less than the limit of quantification (10 mg/L) to 42% of nominal during the fish toxicity test, and after 72 hours, were 13-26% of nominal during the algal growth test.

It is also noted that during the water solubility test (section 3.1), when the test material was added to distilled water above concentrations of 150 g/kg, the solutions initially formed a viscous paste, and as more material was added, it formed a solid mass. The viscous solutions contained significant quantities of undissolved material.

The results of the toxicity test indicate the test material is not toxic to aquatic organisms at the concentrations able to dissolve in water. It is noted that the impurity in the test substance found during analysis of the test media used in the fish and algae toxicity tests is not evident in the GPC trace of the test material used in the hydrolysis test. Its presence was also not reported in the test substance used in the *Daphnia* test.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Usage patterns indicate that ultimately all of the notified polymer will be released to the environment bound to printed paper. At the end of its useful life, most of the printed paper will be either buried in landfill, incinerated, or recycled. A small amount of the polymer will enter the soil environment directly at landfill sites when spent cartridges are disposed of with normal office garbage.

Recycling trends indicate that up to 92% of paper could be recycled in Australia, suggesting a large proportion of the new polymer will enter sewage treatment plants in effluent generated from the de-inking process during paper recycling. The low octanol-water partition coefficient and high water solubility indicate that, in sewage treatment plants, the polymer will be predominantly distributed in water, where it will become diluted and dispersed. Under certain pH conditions, the polymer may form a precipitate and partition into sludge.

A worst case scenario Predicted Environmental Concentration (PEC) is calculated below. In calculating the PEC value, it is assumed that:

- all of the annual imported volume of the notified polymer is deposited on paper, of which 92% is recycled;

- all recycled paper enters paper making facilities at one time, but facilities are distributed nationwide;
- 60% of ink is released into the sewer during the de-inking process, with no precipitation of soluble components occurring.

Annual Import Volume	2500 kg
Volume Fixed to Paper (100%)	2500 kg
Volume in Recycled Paper (92%)	2300 kg
Volume released to Sewage by De-inking (60%)	1380 kg
National Population	18 million
Daily Water Usage per Person 150 L	150 L
PEC	0.5 mg/L

This PEC will be further reduced upon release to the receiving waters. The PEC is a worst case scenario value. In reality, a number of factors could decrease the release rates, thereby further reducing the PEC value. For example, during the toxicity tests, the notified polymer was observed to precipitate in tap water, suggesting the substance will partition to some extent in the presence of ionic substances in solution, and hence, a portion could be removed with solid wastes. It is also likely that the 92% rate for paper recycling is overestimated. Waste Management Industry, Australia (cited in ABS, undated), gave an average recycling rate for paper for the year 1996-1997 of only 28%, although it is recognised that recycling trends are increasing each year. Release of the imported volume of polymer are also not expected to occur at one time, as assumed when calculating the PEC, but would be distributed over a longer period of time, dependent on the turnover time of the printed paper.

The worst case scenario PEC value is several orders of magnitude below the highest concentrations used in the toxicity test, which showed no adverse effects toward aquatic organisms. Hence the polymer is not expected to be toxic to aquatic organisms. The polymer is also not expected to bioaccumulate given its low P_{ow} and high molecular weight, which would preclude any appreciable absorption across biological membrane. As such, the safety margins toward aquatic organisms are expected to be high.

The notified polymer was not readily biodegradable, however, slow biotic and biotic processes are expected to eventually degrade the polymer in the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

Based on the toxicological data provided, the notified polymer would not be acutely toxic via the oral or dermal routes. It is not likely to be a skin sensitiser or genotoxic. It is not likely to be a skin irritant but could be a slight to moderate eye irritant. Upon repeated exposure, organ or systemic effects are not expected. The notified polymer would not be classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999) in terms of the toxicological data provided.

Occupational Health and Safety

Exposure to printing inks containing the notified polymer during transport of pre-filled cartridges should not result in exposure except in the event of accidental spillage.

The notified polymer will be in imported inkjet cartridges at a maximum of 2%. Dermal exposure of office workers to the notified polymer will potentially occur when replacing spent cartridges and clearing paper jams from the printer. However, the design of the cartridges is such that exposure to the notified polymer should be negligible.

Dermal exposure of maintenance workers to the notified polymer is possible during routine maintenance but is expected to be low due to the low concentration of the notified polymer in the ink. Inhalation exposure of maintenance workers to the notified polymer is also possible during routine maintenance. Again the exposure is expected to be low due to the particle size distribution for this polymer being greater than 100 μm and the low concentration of the notified chemical in the ink.

It is concluded that the risk of eye irritation in workers involved in transport, storage, use and disposal of the notified polymer in this application is low.

Due to their frequent exposure to inks and toners, maintenance and printer personnel should wear cotton or disposable gloves and ensure adequate ventilation is present during routine maintenance and repairs.

In the event that the notified polymer will be handled as a raw ingredient at high concentrations, workers should be protected from skin contamination because it has staining properties.

Public Health

At most stages in the acquisition and use of the ink jet cartridges containing the notified polymer, human contact with the notified polymer is minimised. It is imported as a component of ink at a very low concentration in an ink jet cartridge and remains there in an inaccessible state until its imprinting on paper. Public exposure will be most likely limited to transient and infrequent dermal contact which may occur with attempts to insert or remove a damaged cartridge or to remove a paper jam. The notified polymer is itself of very low toxicity. On the basis of the above information, it is considered that the notified polymer will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

To minimise occupational exposure to Lexmark acrylic terpolymer the following guidelines and precautions should be observed:

- Protective eyewear, clothing and gloves should be worn when handling the notified polymer;
- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

No special precautions are required for the notified polymer when used at low quantities in printer cartridges. However, in the interests of good occupational health and safety, the following guidelines and precautions should be observed:

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.

If products containing the notified polymer are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

13.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

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.

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Attachment 1

The Draize Scale (Draize, 1959) 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 (Draize *et al*., 1944) 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

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