

File No: NA/824

February 2001

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

**1,4-Benzenedicarboxylic acid, polymer with 1,3-dihydro-1,3-dioxo-5-isobenzofurancarboxylic acid, dimethyl 1,4-benzenedicarboxylate, formaldehyde, 2,5-furandione, α , α' -[(1-methylethylidene) di-4,1-phenylene] bis[ω -hydroxypoly (oxy-1,2-ethanediyl)], α , α' -[(1-methylethyldiene) di-4,1-phenylene] bis[ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)]], oxirane and phenol
(HIMER EP-208)**

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.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

1,4-Benzenedicarboxylic acid, polymer with 1,3-dihydro-1,3-dioxo-5-isobenzofurancarboxylic acid, dimethyl 1,4-benzenedicarboxylate, formaldehyde, 2,5-furandione, α , α' -[(1-methylethylidene) di-4,1-phenylene] bis[ω -hydroxypoly (oxy-1,2-ethanediyl)], α , α' -[(1-methylethyldiene) di-4,1-phenylene] bis[ω -hydroxypoly[oxy(methyl-1,2-ethanediyl)]], oxirane and phenol (HIMER EP-208)

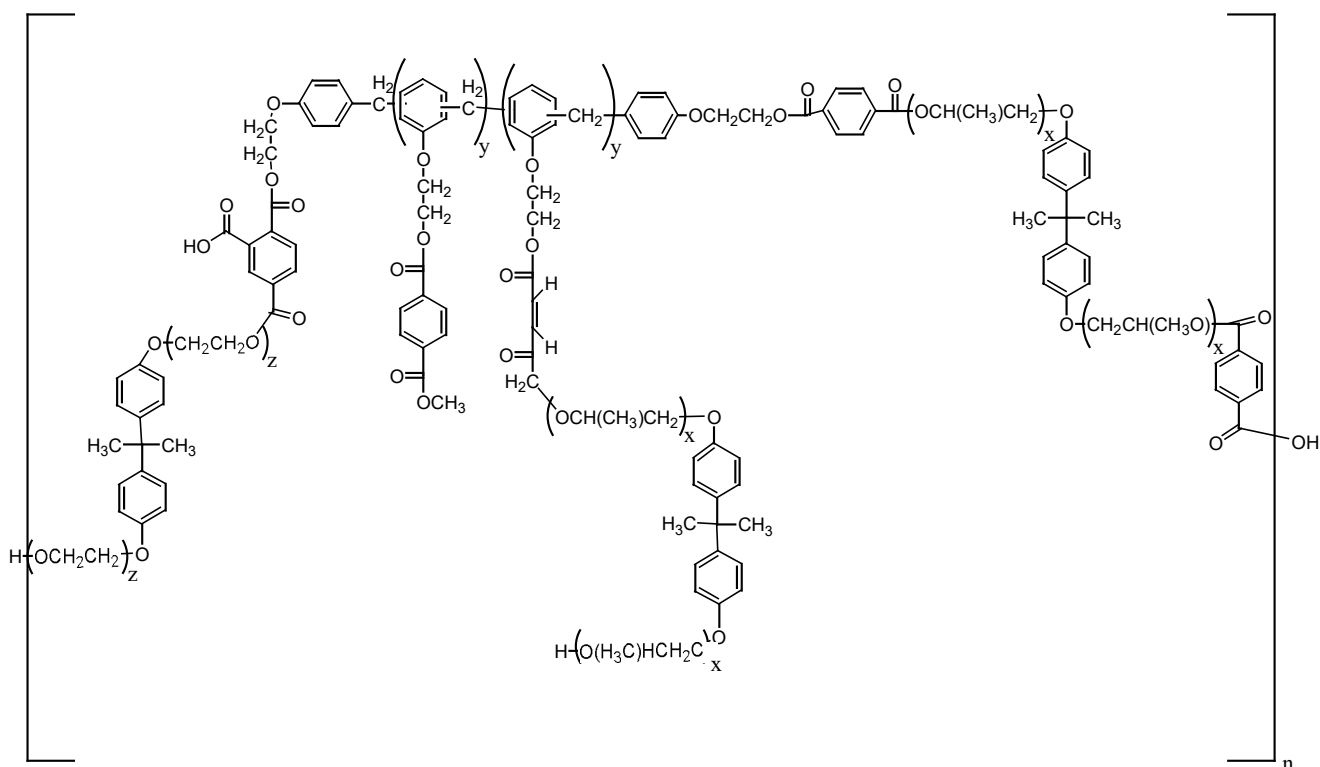
1. APPLICANT

Sharp Corporation of Australia Pty Ltd of 1 Huntingwood Drive, Huntingwood NSW 2148 (ACN: 003039 405) has submitted a limited notification statement in support of their application for an assessment certificate for 'HIMER EP-208'. No application for information relating to 'HIMER EP-208' to be exempt from publication in the Full Public Report and Summary Report was received.

2. IDENTITY OF THE POLYMER

Polymer Name:	1,4-Benzenedicarboxylic acid, polymer with 1,3-dihydro-1,3-dioxo-5-isobenzofurancarboxylic acid, dimethyl 1,4-benzenedicarboxylate, formaldehyde, 2,5-furandione, α , α' -[(1-methylethylidene) di-4,1-phenylene] bis[ω -hydroxypoly (oxy-1,2-ethanediyl)], α , α' -[(1-methylethyldiene) di-4,1-phenylene] bis[ω -hydroxypoly [oxy (methyl-1,2-ethanediyl)]], oxirane and phenol
Polymer Abstracts Service (CAS) Registry No.:	213077-22-6
Other Names:	Terephthalic acid, polymer with trimellitic anhydride, α , α' -[(1-methylethylidene) di-4,1-phenylene] bis[ω -hydroxypoly (oxy-1,2-ethanediyl)], α , α' -[(1-methylethylidene) di-4,1-phenylene] bis[ω -hydroxypoly [oxy (methyl-1,2-ethanediyl)]], dimethyl terephthalate, maleic anhydride, formaldehyde, ethylene oxide and phenol
Marketing Name:	HIMER EP-208
Molecular Formula:	$((C_3H_6O)_x(C_3H_6O)_x C_{15}H_{16}O_2.(C_2H_4O)_z(C_2H_4O)_z C_{15}H_{16}O_2.(C_6H_6O.C_2H_4O.CH_2O)_y.C_9H_4O_5.C_8H_6O_4.C_4H_2O_3.C_{10}H_{10}O_4)_n$

Structural Formula:



Number-Average Molecular Weight (NAMW): 4 300 (GPC Method)

Weight-Average Molecular Weight: 740 000 (GPC Method)

Maximum Percentage of Low Molecular Weight Species

Molecular Weight < 500: 1.6 %
Molecular Weight < 1 000: 5.0 %

Weight Percentage of Ingredients:

<i>Polymer Name</i>	<i>CAS No.</i>	<i>Weight %</i>
Poly(oxy-1,2-ethanediyl), α , α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -hydroxy-1,4-Benzenedicarboxylic acid	32492-61-8	8.2
	100-21-0	18.4
Poly[oxy(methyl-1,2-ethanediyl)], α , α' -[(1-methylethylidene) di-4,1-phenylene]bis[ω -hydroxy-Formaldehyde, polymer with oxirane and phenol	37353-75-6	55.3
	25134-84-3	3.8

5-Isobenzofurancarboxylic acid, 1,3-dihydro-1,3-dioxo-	552-30-7	5.2
2,5-furandione	108-31-6	2.7
1,4-Benzenedicarboxylic acid, dimethyl ester	120-61-6	6.4

Method of Detection and Determination:

¹H NMR, UV spectrum and IR spectrum

Spectral Data:

¹H NMR polymer group shifts at: 8.2, 7.2, 6.8, 5.5, 4.7, 4.0, 3.8, 1.5 to 1.3 ppm. UV; broad band at 280 nm.

3. PHYSICAL AND POLYMER PROPERTIES

The following are for the notified polymer, unless otherwise specified.

Appearance at 20 °C & 101.3 kPa: The notified polymer is a lightly yellow, granular solid with no specific odour.
The toner product containing the notified polymer is a fine, black odourless powder.

Softening Point: approximately 170°C

Specific Gravity: Approximately 1.2 x 10³ kg/m³ at 20°C

Vapour Pressure: Not provided: the notified polymer is a solid at 25°C

Water Solubility: approximately 1 mg/L

Partition Co-efficient (*n*-octanol/water): Not determined

Hydrolysis as a Function of pH: Stable

Adsorption/Desorption: Not determined

Dissociation Constant: Not determined

Particle Size: Polymer = 93.4 % > 45 µm; 4.3% > 500 µm; Average = 180 µm.
Toner = 8.7 µm.
Carrier = 100 µm.

Flash Point: > 200 °C (Cleveland open cup method)

Flammability Limits: Not provided: Not expected to be flammable.

Autoignition Temperature: Not provided: Not expected to autoignite.

Explosive Properties: Not provided: Not expected to be explosive.

Reactivity/Stability: Not provided: Expected to be stable.

Comments on Physico-Polymer Properties

The vapour pressure was not determined as the notified polymer has a high molecular weight and is solid at room temperature. Thus, the vapour pressure is expected to be negligible.

Water solubility was determined using a modified flask method where the polymer was added to water and the remaining solid material was filtered, dried and weighed. This method indicated that the solubility of the notified polymer is ~1 mg/L.

Hydrolysis as a function of pH was determined using a modified flask method. The polymer was placed in buffered solutions at pH 1.2, 4.0, 7.0 and 9.0 at 40°C (prepared according to OECD TG 111) and the solubility was determined as described above. After two weeks there was no significant change compared with the water solubility. The polymer is believed to be stable in the environmental pH range.

While the partition coefficient was not determined due to the low water and octanol solubility of the polymer at 25°C, the octanol solubility was measured as 1 mg/L, suggesting that the notified polymer will not partition significantly between the aqueous and organic phases.

Adsorption/desorption was not determined due to the low water solubility of the notified polymer. It is thought that the polymer will become associated with soil and sediments.

No dissociation constant data was provided. The polymer contains a very small amount of aromatic carboxylic acid functional groups, which are expected to have typical acidity and dissociate. However, the insoluble nature of the polymer should prevent extensive dissociation.

4. PURITY OF THE POLYMER

Degree of Purity: > 99 wt %

Hazardous Impurities: None

Non-hazardous Impurities (> 1% by weight):

Chemical name: Stannane, dibutyloxo-

Synonyms:

Weight percentage: <1.6%

CAS No.: 818-08-6

Chemical name: Water

Synonyms:

CAS No.: 7732-18-5

Weight percentage: 0.2%

Maximum Content of Residual Monomers:

<i>Polymer Name</i>	<i>CAS No.</i>	<i>Weight %</i>
Poly(oxy-1,2-ethanediyl), α , α' -(1-methylethylidene)di-4,1-phenylene]bis[ω -hydroxy-	32492-61-8	<1.6
1,4-Benzenedicarboxylic acid	100-21-0	
Poly[oxy(methyl-1,2-ethanediyl)], α , α' -(1-methylethylidene) di-4,1-phenylene]bis[ω -hydroxy-	37353-75-6	
Formaldehyde, polymer with oxirane and phenol	25134-84-3	
5-Isobenzofurancarboxylic acid, 1,3-dihydro-1,3-dioxo-	552-30-7	
2,5-furandione	108-31-6	
1,4-Benzenedicarboxylic acid, dimethyl ester	120-61-6	

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified polymer will be imported in 100 g sealed toner cartridges or 700 and 800 g bottles as a component of toners (AR-400NT, AR-400ST and AR-400T) and developers (AR-400ND, AR-400SD and AR-400DV) used in photocopiers, laser printers and fax machines. The notified polymer is used as a toner binding agent for fixing electrophotographic images onto a sheet of paper. The notified polymer is present in the toners at 85-89% and in the developers at 3.55%. Both the toners and developers are imported as a fine black powder.

The notified polymer will be imported at a projected rate of 2.77 tonnes/year for the first five years.

All manufacturing, formulation and packaging of the toners and developers will be performed prior to importation.

At the time of this assessment the notified polymer was in use in Australia under a NICNAS Commercial Evaluation permit (Permit No.:427) granted under section 21G of the Act.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

The notified polymer will be imported as a component of toners and developers. The toners and developers will be transported by road in bottles or cartridges sealed in plastic bags for distribution to customers in the printing industry. Waterside, warehouse and transport workers are unlikely to be exposed to the notified polymer during transportation and storage except in the event of an accident.

Service Personnel

Duties of the service personnel will include cleaning the inside of the machine and servicing the machine (particularly the exterior of the processing unit), and replacement of copier developer. The notifier estimated total exposure time for an individual to be 47 hours per year, based on 187 services and 0.25 hours per service. Both inhalation and dermal exposure to the toner powder may occur during these activities.

Office Workers

Printing and/or office staff would add copier toner to the hopper once a month and replace the toner cartridge every four months (160 000 copies) for a total anticipated exposure of 12 minutes/year. As the pre-packaged toner bottles and cartridges are sealed, the likelihood of dermal or inhalation exposure to the notified polymer during toner replacement should be low. Spent toner cartridges are disposed of through general office waste. During printing, less than 50 mg of toner is transferred to each paper sheet and heat-cured, limiting the potential for dermal exposure to the notified polymer from printed material.

If toner is spilt while changing cartridges or bottles, exposure may occur. In the event of a spill, dermal and inhalation exposure to the notified polymer is expected to be high for the toner (85-89% notified polymer) and low for the developer (3.55% notified polymer). However, as the binder product has a large mean particulate size of 180 μm (95 % > 45 μm), the risk of respirability is low. Dermal exposure may also occur when clearing paper jams and other minor fax, printer and photocopier mechanical failures.

Control of Exposure

No personal protective equipment has been recommended by the notifier. The Material Safety Data Sheet (MSDS) states that a dust mask should be used while handling a large quantity of toner or during long term exposure to the notified polymer.

Health Conditions and Adverse Effect Reporting

The notifier advised that the notified substance is not known to cause any health conditions or to affect any existing health conditions.

7. PUBLIC EXPOSURE

Public exposure to the notified polymer will occur during the filling of toner or developer bottles and the changing of toner cartridges in photocopiers/printers/faxes. There will also be contact with printed media containing the notified polymer. Consequently, any exposure is likely to be dermal and/or by inhalation, with the possibility of ocular and oral exposure.

8. ENVIRONMENTAL EXPOSURE

Release

Under normal use the toner/developer containing the notified polymer is transferred onto a sheet of paper where it is firmly fixed to the surface by heat. Release to the environment will be negligible. Waste paper containing the toner/developer will eventually be sent to landfill, recycled or incinerated.

Release of the notified polymer will also occur through the disposal of bottles containing residues of the toner/developer. Though the notifier has indicated that 1 g of residue is left in a toner/developer container (~0.15% of original contents), experience suggests that, depending on the design of the bottles, residual toner levels of up to 1% are more realistic. The expected volume of residue remaining in cartridges may be up to 7 g. However, as the toner contains 89% of the notified polymer, the maximum quantity of polymer released in this fashion would be 6.3 g per bottle. This represents a maximum of up to 28 kg of the notified polymer per year on current import volume projections. The spent bottles will be disposed of to landfill, a process which would be widespread across Australia.

Additional release to the environment will result from disposal of the used toner container from the photocopy machine. This will amount to up to 123 kg per year, approximately 5% of the import quantity. The used toner would be disposed of through general office waste, with most going to landfill.

Fate

Some waste paper may be disposed of directly to landfill with the notified polymer strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified polymer. Incineration of waste paper will destroy the polymer with the generation of water vapours and oxides of carbon.

Printed paper may also be recycled. The notifier has provided no data on the likely behaviour of the polymer during the paper recycling process. During such processes, waste paper is repulped and de-inked. De-inking wastes are expected to go to trade waste sewers.

The low water solubility of the notified polymer suggests that any released to the aquatic compartment will associate with sediments and soils. Polymer disposed of to landfill is unlikely to leach or contaminate surface water.

Due to the large molecular weight of the notified polymer, it is not expected to cross biological membranes or bioaccumulate.

9. EVALUATION OF TOXICOLOGICAL DATA

The notifier has not submitted toxicity studies using the notified polymer. Instead the notifier has submitted toxicity studies using the Toner product AR-ST17-B, which contains the notified polymer at >85%. The studies are accepted as providing a reasonable indication of the toxicity of the polymer.

9.1 Acute Toxicity

Summary of the acute toxicity of AR-ST17-B

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
Acute oral toxicity	rat	>2000 mg/kg	Environmental Biological Life Science Research Centre, 1998a
Skin irritation	rabbit	Non irritating	Environmental Biological Life Science Research Centre, 1998b
Eye irritation	rabbit	Non irritating	Environmental Biological Life Science Research Centre, 1998c

9.1.1 Oral Toxicity (Environmental Biological Life Science Research Centre, 1998a)

<i>Species/strain:</i>	Rat/Sprague-Dawley
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	14 days
<i>Method of administration:</i>	Oral (gavage) of 2 000 mg/kg of body weight in female and male rats.
<i>Test method:</i>	OECD TG 401
<i>Mortality:</i>	No deaths occurred during the observation period.
<i>Clinical observations:</i>	Black staining of the hair around the anus on day one after dosing was observed in all animals.
<i>Morphological findings:</i>	No morphological abnormalities were detected in all animals sacrificed at day 14.
<i>Comment:</i>	Normal bodyweight gains were observed for all animals.
<i>LD₅₀:</i>	>2000 mg/kg bodyweight.
<i>Result:</i>	The notified polymer was of very low acute oral toxicity in rats.

9.1.2 Skin Irritation (Environmental Biological Life Science Research Centre, 1998b)

Species/strain: Rabbit/New Zealand Albino

Number/sex of animals: 3

Observation period: 3 days

Method of administration: A semi-occlusive application of 0.1 g test substance moistened with a little water was made on the dorsal skin. After 4 hours, the substance was carefully removed with 70% ethanol.

Test method: OECD TG 404

Draize scores:

<i>Time after treatment (days)</i>	<i>Animal #</i>	
<i>1</i>	<i>2</i>	<i>3</i>
<hr/>		
<i>Erythema</i>		
all scores were zero		
<hr/>		
<i>Oedema</i>		
all scores were zero		
<hr/>		

^a see Attachment 1 for Draize scales

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

9.1.3 Eye Irritation (Environmental Biological Life Science Research Centre, 1998c)

Species/strain: Rabbit/New Zealand Albino

Number/sex of animals: 3

Observation period: 3 days

Method of administration: A single dose of 0.1 g of test substance was applied to the conjunctival sac of the right eye of each animal, with the left untreated eye serving as control.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

Time after instillation

<i>Animal</i>	<i>1 day</i>	<i>2 days</i>	<i>3 days</i>
<i>Cornea</i>	all scores were zero		
<i>Iris</i>	all scores were zero		
<i>Conjunctiva</i>	all scores were zero		

Comment: Eye irritation was not observed in all animals tested.

Result: The notified polymer was not irritating to the eyes of rabbits.

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Environmental Biological Life Science Research Centre, 1998d)

Strains: *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100 and *Escherichia coli* strain WP2 *uvrA*

Metabolic activation: Liver fraction (S9 mix) from rats pretreated with phenobarbital and β -benzoflavone

Concentration range: Dose ranging study;
0, 0.3, 1.2, 4.9, 19.5, 78.1, 312.5, 1 250 and 5 000 $\mu\text{g}/\text{plate}$.
Main Study;
0, 156.3, 312.5, 625, 1 250, 2 500 and 5 000 $\mu\text{g}/\text{plate}$.
Each concentration was tested with and without the presence of metabolic activator.
Each data point was tested in duplicate.
Appropriate strain specific control reference substances were used.

Test method: OECD TG 471

Comment: A stock solution of the test article at 100 mg/mL was prepared in acetone.
In the dose ranging study the test article was found to precipitate at $\geq 78.1 \mu\text{g}/\text{plate}$ in the absence of metabolic activator and $\geq 312.5 \mu\text{g}/\text{plate}$ in the presence of metabolic activator. In the main study the test article was found to precipitate at all concentrations in the absence of metabolic activator and $\geq 312.5 \mu\text{g}/\text{plate}$ in the presence of metabolic activator.
Bacterial growth was not inhibited by precipitation of the test article.

Result: The notified polymer was non mutagenic under the conditions of the test.

9.3 Overall Assessment of Toxicological Data

The notifier submitted toxicity studies using the Toner product AR-ST17-B, which contains the notified polymer at >85%.

The product AR-ST17-B has very low acute oral toxicity ($LD_{50} > 2\,000$ mg/kg) in rats. Acute dermal toxicity and acute inhalation studies have not been conducted for the notified polymer or the product AR-ST17-B. In rabbits, the product AR-ST17-B was not a skin or eye irritant. No sensitisation or repeat dose toxicity studies have been conducted using the notified polymer or the product AR-ST17-B.

As indicated in the MSDS for the notified polymer and the product AR-400NT, mechanical irritation of the eyes and inflammation and irritation of the respiratory tract may result from exposure to the notified polymer in dust form as well as the toner or developer containing the notified polymer.

Although the toner product AR-ST-17B revealed no mutagenic activity in a bacterial test system, it should be noted that the test substance was found to precipitate at all concentrations in the absence of metabolic activator and at concentrations above 312.5 µg/plate in the presence of metabolic activator. It is noted that the MSDS for the product AR-400NT states that a two-year cancer study using a typical toner preparation containing carbon black demonstrated no association between toner exposure and tumour development in rats.

Based on the data submitted the notified polymer could not be classified as a hazardous substance against the *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicology data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified polymer will enter environmental compartments indirectly *via* disposal of waste paper for recycling, to landfill or for incineration, and directly from release from discarded spent bottles at landfill sites and sludge from paper recycling processes. Release of the notified polymer to the environment is expected to be low and widespread.

Following accidental spillage of the toner, either during filling of toner hoppers or during transport, powder wastes should be sent to either landfill or incineration facilities.

The notified polymer is expected to be immobile in soils, sediments and landfill sites and should not partition to the aquatic environment because of its low water solubility.

On the basis of the available information the overall environmental hazard of the notified polymer is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified polymer is a powder of mean particulate size of 180 µm (95 % > 45 µm), ie it is possibly inspirable but not respirable.

The toner product AR-ST17-B, which contains the notified polymer at >85%, is of very low acute oral toxicity in rats (LD₅₀ > 2 000 mg/kg), was not a skin or eye irritant and did not result in mutagenic activity in an Ames test.

Acute dermal and acute inhalation toxicity studies, skin or respiratory sensitisation studies, and chromosome aberration studies have not been conducted for the notified polymer or the product AR-ST17-B.

Based on the limited toxicological data supplied for the notified polymer the substance cannot be classified as a hazardous substance against the *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission 1999).

Occupational Health and Safety

There is little potential for significant occupational exposure to the notified polymer in the transport and storage of the toner and developer products that contain the notified polymer.

Service personnel may experience inhalation and dermal exposure to toner and developer powders while cleaning and servicing the inside of photocopiers, printers and fax machines (particularly the exterior of the processing unit). As there may be a low level of toner and developer dust inside photocopiers, printers and fax machines, service personnel should wear personal protective equipment, such as a dust mask, to limit inhalation exposure to the notified polymer. The high molecular weight of the notified polymer indicates that dermal absorption would be minimal.

Office workers may experience infrequent dermal exposure when changing the toner or developer, while clearing paper jams or cleaning up small spills. Due to the enclosed design of toner cartridges and the short duration required to perform these functions, exposure to the notified polymer should be minimal. The instructions on the cartridge label and instruction sheet on how to insert a new cartridge should be followed. The high molecular weight of the notified polymer indicates that dermal absorption would be minimal. As there may be a low level of toner and developer dust in the immediate vicinity of photocopiers, faxes and printers when they are operating, the area around them should be well ventilated.

Based on the low toxicological hazard presented by the polymer and the expected low

exposures, the health risk posed to service personnel and office workers by the notified polymer is low.

However, it should be noted that the toners and developers, which contain the notified polymer, also contain potentially hazardous ingredients such as carbon black, iron oxide and magnesium oxide. It is important that appropriate measures are taken to control any occupational exposure to these components. Employers should ensure that the exposure standards for these agents are adhered to in the workplace.

Public Health

Public exposure to the notified polymer will predominantly occur from dermal contact with printed media. Once printed, the notified polymer is heat-cured onto paper making it biologically unavailable. Occasional exposure will also occur from the filling of toner or developer bottles and changing of toner cartridges. A mean particle size of 180 µm (95% >45 µm) greatly reduces the potential inhalation hazard; consequently the main toxicological hazard is likely to be mechanical irritation by inert particulate material to the eye or the respiratory system. Therefore, the potential hazard to the public throughout of the life of the notified polymer is considered to be low.

13. RECOMMENDATIONS

To minimise occupational exposure to HIMER EP-208 the following guidelines and precautions should be observed:

- Service personnel should wear a disposable dust mask to minimise inhalation exposure to the toner or developer;
- Photocopies, faxes and printers utilising toners and developers containing the notified polymer should be located in a well ventilated area when operating to minimise the concentration of airborne particles;
- Employers should ensure that the exposure standards for ingredients in the toners and developers are adhered to in the workplace;
- Spillage of the notified polymer should be avoided. Spillages should be swept or wiped promptly and put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for HIMER EP-208 and the toner and developer products containing HIMER EP-

208 were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

A sample MSDS for a toner product containing HIMER EP-208 is published in the assessment report. The accuracy of the information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of HIMER EP-208 may be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

Connell D W, 1989. 'General characteristics of organic compounds which exhibit bioaccumulation'. In Connell D W, (Ed) *Bioaccumulation of Xenobiotic Compounds*. CRC Press, Boca Raton, USA.

Environmental Biological Life Science Research Centre, Inc. (1998a) Acute oral toxicity of Toner (AR-ST17-B, AR-330CT, AR-330LT) for AR-330MT series in Rat. Report No. 2731, (English Translation) Japan.

Environmental Biological Life Science Research Centre, Inc. (1998b) Primary dermal irritation test of Toner (AR-ST17-B, AR-330CT, AR-330LT) for AR-330MT series in Rabbits. Report No. 2732, (English Translation) Japan.

Environmental Biological Life Science Research Centre, Inc. (1998c) Primary ocular irritation test of Toner (AR-ST17-B, AR-330CT, AR-330LT) for AR-330MT series in Rabbits. Report No. 2733, (English Translation) Japan.

Environmental Biological Life Science Research Centre, Inc. (1998d) Bacterial reverse mutation test of Toner (AR-ST17-B, AR-330CT, AR-330LT) for AR-330MT series. Report No. 2734, (English Translation) Japan.

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

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

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

<i>Erythema Formation</i>	<i>Rating</i>	<i>Oedema Formation</i>	<i>Rating</i>
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

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

<i>Values</i>	<i>Rating</i>
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

MSDS