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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in HP Scitex Printer Ink Series

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

Polymer in HP Scitex Printer Ink Series

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
CPI Graphics Ltd (ABN 54 004 081 501)
41 – 45 Mills Road
BRAESIDE VIC 3195

DIC Australia Pty Ltd (ABN 12 000 079 550)
42 Sunmore Close
HEATHERTON VIC 3202

Hewlett-Packard Australia Pty Ltd (ABN 74 004 394 763)
353 Burwood Highway
FOREST HILL VIC 3131

Huntsman Corporation Australia Ltd (ABN 67 083 984 187)
454-460 Somerville Road
WEST FOOTSCRAY VIC 3012

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: Chemical Name, CAS Number, Molecular and Structural Formulae, Molecular Weight, Polymer Constituents, Additives/Adjuvants, Use Details, Import Volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: Melting Point, Boiling Point, Vapour Pressure, Water Solubility, Hydrolysis as a function of pH, Partition Co-efficient, Adsorption/Desorption, Dissociation Constant, Flammability Limits, Autoignition Temperature, Explosive Properties.

NOTIFICATION IN OTHER COUNTRIES
EU, Korea

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
HP Scitex TJ200 Black Ink
HP Scitex FB260 Yellow Ink
HP Scitex FB221 Cyan Ink

OTHER NAME(S)
Alkylphenoxypolyalkyloxyamine

MOLECULAR WEIGHT
Mn >1000 Da.

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Amber liquid

Property	Value	Data Source/Justification*
Melting Point/Freezing Point	Liquid at room temperature	Not determined
Boiling Point	872 ± 65°C at 101.3 kPa	Calculated (US EPA, 2009)
Relative Density	999 kg/m^3	MSDS
Vapour Pressure	3.29×10^{-6} kPa to 2.03×10^{-22} kPa at 25°C	Calculated (US EPA, 2009)
Water Solubility	6.911×10^{-4} g/L to 6.113×10^{-10} g/L	Calculated (US EPA, 2009)
Hydrolysis as a Function of pH	Not determined	No hydrolysable functions
Partition Coefficient (n-octanol/water)	log Pow = 5.91 to 7.63	Calculated (US EPA, 2009)
Adsorption/Desorption	log K_{oc} > 4.45	Calculated (US EPA, 2009)
Dissociation Constant	Not determined	Contains a group with pKa > 10
Particle Size	Not determined	The notified polymer is a liquid
Flash Point	193°C	MSDS
Flammability	Not predicted to be flammable	Estimated based on flash point
Autoignition Temperature	Not predicted to auto-ignite	Estimated based on flash point
Explosive Properties	Not predicted to be explosive	Estimated based on polymer structure.

* No test data were provided on the physical and chemical properties of the notified polymer.

DISCUSSION OF PROPERTIES

Dangerous Goods classification

Based on the submitted physical-chemical data in the above table the notified polymer is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above does not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the polymer.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will not be manufactured in Australia but imported as a component of UV-curable inks at a maximum concentration of up to 1%.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.5	< 0.5	< 0.5	< 0.5	< 0.5

PORT OF ENTRY

Sydney, Melbourne

TRANSPORTATION AND PACKAGING

Ink containing the notified polymer will be imported in 5 L plastic bottles and transported by road to warehouses for storage before distribution to various customers.

USE

The notified polymer will be used as a component of UV-curable inkjet printing inks at concentrations up to 1%.

OPERATION DESCRIPTION

The notified polymer will not be manufactured, reformulated or repackaged in Australia.

The finished inks containing the notified polymer up to 1% will be transported to the notifier's storage facilities and then to industrial printing companies. The inks will be used in industrial printers for the digital printing of large format images on a variety of substrates.

Ink bottles containing the notified polymer will be manually connected to the printing machine via an inlet and attached to a flexible tube which supplies the ink head. Separate ink bottles will be provided for each of the required colours for printing. Inks will be automatically injected into printing machines. Trained service technicians will handle all products containing the notified polymer.

While printers are running, print operators will monitor their operation, keep the substrate (eg. vinyl, paper) feeders stocked, attend to substrate jams and conduct quality control. Any residual ink within printing equipment will be wiped clean using rags and solvents. These rags and dirty solvents are expected to be disposed of by the printing company through licensed waste disposal contractors.

After printing, the notified polymer will be fixed (UV-cured) with other ink ingredients onto the substrate matrix, and subsequently not expected to be available for release.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storages	10-20	4-8	200
Print operators	> 1000	0.5	5
Service technicians	200	8	200
Wholesale printer supplies	> 1000	8	200

EXPOSURE DETAILS

Transport, Warehousing and Wholesale Printer Supply Workers

Workers are not expected to be exposed to the notified polymer, as it will be transported in sealed containers. Exposure is possible in the event of an accident where the packaging is breached.

Print operators

Print operators are not expected to be exposed to the notified polymer in imported printing inks, as the process will be mainly automated. However, dermal exposure to small amounts of the notified polymer may occur during the manual attachment and replacement of ink bottles to printing machines. Inhalation exposure may also occur to aerosols of the notified polymer during the operation of the printers. However, this is expected to be minimised using local exhaust ventilation installed in areas surrounding the printing machines.

Service technicians

Service technicians may experience dermal exposure to the notified polymer during printer maintenance but this is expected to be minimized by the use of cotton gloves. Inhalation exposure may also be possible but will be minimized through the use of local exhaust ventilation.

After application to the substrate, the ink containing the notified polymer will be UV-cured (fixed) and hence no longer available for exposure.

6.1.2. Public exposure

Neither the printer inks nor the printed materials containing the notified polymer will be sold to the public. Once cured onto the substrate, the notified polymer is expected to remain bound to the substrate print matrix. Thus, public exposure resulting from the use of the notified polymer is expected to be negligible.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 = 2135.3 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 >3000 mg/kg bw; low toxicity
Rabbit, skin irritation	severely irritating
Rabbit, eye irritation	severely irritating
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* <mammalian chromosome aberration>	non genotoxic

Toxicokinetics, metabolism and distribution.
The notified polymer has a molecular weight of >1000 Da., is insoluble in water (6.911×10^{-4} g/L to 6.113×10^{-10} g/L) and has a high log Pow (5.91 to 7.63). However, there is a significant portion of species with molecular weight <1000 Da and it is therefore expected to have some potential to be absorbed via the oral route possibly through micellular solubilisation. This is partially confirmed by the effects seen in some animals in the acute oral toxicity test. There is only a small percentage of low molecular weight species (<500 Da) in the notified polymer and therefore dermal absorption is not expected.

Acute toxicity
In an acute oral toxicity study in rats, the notified polymer caused mortalities at all dose levels (2000, 3200 and 5000 mg/kg bw) and the LD50 was calculated to be 2135.3 mg/kg bw. Decreased activity, abnormal gait and stance, diarrhoea, dyspnea, poor grooming, decreased body tone, chromodacryorrhea, distended abdomen and prostration were observed following oral administration. Necropsy of animals dying as a result of treatment with the notified polymer found that the stomachs and intestines were fluid-filled or distended and the liver and kidneys were discoloured.

The notified polymer was found to be of low acute dermal toxicity in rats.

Irritation and Sensitisation.
The notified polymer was found to be severely irritating to the skin and eyes of rabbits.

The notified polymer was not tested for its potential to elicit skin sensitisation. It does not contain any known structural alerts for skin sensitisation (Barratt et al. 1994) and is therefore not expected to be a skin sensitiser.

Mutagenicity
The notified polymer was not found to be mutagenic and not clastogenic to Chinese Hamster Lung (CHL) cells.

Health hazard classification
Based on the effects observed in the skin and eye irritation studies, the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:
R38 Irritating to skin
R41 Risk of serious damage to eyes

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The main concern for the notified polymer is its potential to cause severe irritation to the skin and eyes.

Workers at industrial printing operations may experience incidental dermal and ocular exposure to inks containing the notified polymer at up to 1% while replacing ink bottles in industrial printing machines. However, exposure is expected to be limited due to the low concentration of the notified polymer in the inks.

Service technicians may be exposed to inks containing the notified polymer at up to1% during maintenance and cleaning of industrial printing machines. These workers are expected to wear cotton gloves to minimise dermal exposure. Ocular exposure is not anticipated but if it did occur the low concentration of the notified polymer (<1%) in the ink residues is not anticipated to lead to serious eye injury.

Wholesale workers are not expected to encounter exposure to the notified polymer during packing and handling of ink bottles containing the notified polymer in ink formulations except in case of an accident.

Overall, the notified polymer is not anticipated to lead to an unacceptable risk to workers in industrial printing operations.

6.3.2. Public health

Neither the inks containing the notified polymer nor substrates containing the cured ink will be sold to the public. Therefore, the risk to public health is not expected based on the low potential for exposure.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured or reformulated within Australia. Therefore, release may only occur during a transport accident and handling of the imported formulated products, and as such is not expected to be significant.

RELEASE OF CHEMICAL FROM USE

Some release is expected to occur during the printing process via cleaning and maintenance operations and small spills. It is expected these residues will be disposed of to landfill. The formulated products containing the notified polymer will be applied to a variety of substrates including paper materials using industrial inkjet printers. The applied notified polymer is expected to be trapped in the ink matrix with other components of the ink.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer is expected to be disposed of to landfill and is expected to remain associated with the substrate to which it has been applied. Of the notified polymer applied to paper, 50% is expected to be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of toner from the fibres.

7.1.2 Environmental fate

The results of a biodegradability study on the notified polymer submitted, indicated that the polymer is not readily biodegradable. Refer to Appendix B for details of this study.

The small amount of notified polymer washed to the sewers as a result of paper recycling is expected to be removed in sewage treatment plants by adsorption to solids based on its estimated high log Pow values, low water solubility and high molecular weight (MW > 1000).

In landfill the notified polymer is expected to degrade slowly via biotic and abiotic processes over time to form predominantly simple organic compounds and water. Leaching of the notified polymer into water is not likely due to its expected low water solubility and high adsorption/desorption coefficient.

7.1.3 Predicted Environmental Concentration (PEC)

Under a worst case scenario, it was assumed that 50% of the paper products containing ink (comprising 5% of the total imported notified polymer) would be recycled and released into sewers and there would be no removal of the notified polymer by the sewerage treatment plant. The resultant Predicted Environmental Concentration (PEC) in sewage effluent nationwide is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	500	kg/year
Proportion expected to be released to sewer	2.5%	
Annual quantity of chemical released to sewer	12.5	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.05	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.011	µg/L
PEC - Ocean:	0.0011	µg/L

7.2. Environmental effects assessment

No ecotoxicity data were submitted. The notified polymer is potentially cationic in the environment and the calculated charge density of the polymer is nominally indicative of a toxic hazard to the aquatic environment. However, due to its expected low water solubility and likelihood for adsorption to particulates, the notified polymer is not expected to be present in water at significant environmental concentrations. The notified polymer is not anticipated to cross biological membranes due to its high molecular weight and is therefore not expected to bioaccumulate.

7.2.1 Predicted No-Effect Concentration

Since no ecotoxicity data were submitted and due to the information outlined in Section 7.2, the predicted no effect concentration (PNEC) was not calculated.

7.3. Environmental risk assessment

The notified polymer is anticipated to be of concern to aquatic organisms due to its potentially cationic functional group. However, the potential for exposure of the notified polymer to the aquatic environment is very low because the majority will be disposed to landfill. The risk for harm to aquatic organisms due to washings to the sewer, as a result of paper recycling, is mitigated by the notified polymer's lack of potential to bioaccumulate, insolubility in water and high propensity to adsorb to particulate matter. Taking into account the low exposure to aquatic organisms, the notified polymer is therefore not expected to pose an unacceptable risk to the environment based on its proposed use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided the notified polymer is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] with the following risk phrases:

R38 Irritating to skin
R41 Risk of serious damage to eyes

and

As a comparison only, the classification of the notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Skin irritant	2	Causes skin irritation
Eye irritant	1	Causes serious eye damage

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the reported use pattern, the notified polymer is not expected to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- Safe Work Australia, should consider the following health hazard classification for the notified polymer:
  - R38 Irritating to skin
  - R41 Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - conc. ≥ 20%: R41 Risk of serious damage to eyes; R38 Irritating to skin
  - ≥ 10% conc. < 20%: R41 Risk of serious damage to eyes
  - ≥ 5% conc. < 10%: R36 Irritating to eyes

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in the HP Scitex Printer Ink Series products:
  - Avoid contact with skin and eyes

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Disposal

- The notified polymer should be disposed of to landfill. Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the notified polymer is intended for use in ink jet printing inks at ≥ 1%; or
- products containing the notified polymer are intended for use by the public.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from component of industrial ink jet printing inks, or is likely to change significantly;
- the amount of the notified polymer being introduced has increased from 0.5 tonne, or is likely to increase, significantly;
- the notified polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet
The MSDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (>98%)
METHOD	US EPA Federal Register, Vol. 50, No. 188, 1985 (equivalent to OECD TG 401 Acute Oral Toxicity.)
Species/Strain	Rat/Sprague-Dawley
Vehicle	None
Remarks - Method	No significant protocol deviations. In a dose-finding study, 3 groups of 2 rats (1 male, 1 female) were dosed with the notified chemical at 500, 2500 and 5000 mg/kg bw. One of the 2 animals died at 5000 mg/kg bw. Based on the dose-finding study, doses chosen for the main study were 2000, 3200 and 5000 mg/kg bw to determine the LD50. The test substance was administered by oral gavage and the rats were observed at approximately 1, 4 and 24 hours after dosing and once daily through to Day 14. The LD50 was calculated according to the Litchfield-Wilcoxon method using the Pharmacologic Calculation System Version 4.1. This was then corrected using the Innovative Programming Associates, LABCAT Module Version 4.22.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 M, 5 F	2000	4/10
II	5 M, 5 F	3200	9/10
III	5 M, 5 F	5000	10/10

LD50	2135.3 mg/kg bw
Signs of Toxicity	Decreased activity, abnormal gait and stance, diarrhoea, dyspnea, poor grooming, decreased body tone, chromodacryorrhea, distended abdomen and prostration were observed in animals at each dose level.
Effects in Organs	Fluid-filled and/or distended stomachs and intestines and discoloured liver and kidneys were observed in the decedents.
CONCLUSION	The notified polymer is of low acute toxicity via the oral route.
TEST FACILITY	Pharmakon (1992a)

A.2. Acute toxicity – dermal

TEST SUBSTANCE	Notified polymer (>98%)
METHOD	US EPA Federal Register, Vol. 50, No. 188, 1985 (similar to OECD TG 402 Acute Dermal Toxicity – Limit Test.)
Species/Strain	Rabbit/New Zealand White
Vehicle	None
Type of dressing	Occlusive
Remarks - Method	Rabbits were used (5 males and 5 females) instead of the recommended species: rat.

RESULTS

LD50	>3000 mg/kg bw
Signs of Toxicity - Local	Erythema, oedema, necrosis, sloughing and/or fissuring of the skin was observed at the site of application.

Signs of Toxicity - Systemic	None observed.
Effects in Organs	None observed.
Remarks - Results	Decreased bodyweight, decreased muscle and an absence of faeces was observed in males. However, it was unclear whether any of these effects were related to treatment. No mortalities were observed during the study.

CONCLUSION The notified polymer is of low acute toxicity via the dermal route.

TEST FACILITY Pharmakon (1992b)

A.3. Irritation – skin

TEST SUBSTANCE Notified polymer (>98%)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 Males, 3 Females
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	The study involved application of the test material at 5 treatment sites per animal. The test material was applied once per non-abraded site (0.5 mL per site) and remained in contact with the skin site for 3 minutes, 60 minutes, 4 or 24 hours. Each animal also had one abraded test site in which the test material remained in contact with the skin for 24 hours. The effects reported in the table below were observed following exposure of animals to the notified chemical for 4 hours.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	2.6	3	>14 days	4
Oedema	2.1	3	>14 days	4

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	Very slight to severe erythema and very slight to moderate edema were observed in all 6 rabbits at removal of the occlusive dressing and at 24, 48, 72 hours as well as Day 4. Necrosis was observed in all animals at the 4 hour test site from Day 6 until the end of the observation period (Day 14). Fissuring and/or sloughing of the skin was also seen in these animals from Day 6 until end of the observation period.

CONCLUSION The notified polymer is severely irritating to the skin.

TEST FACILITY Pharmakon (1993)

A.4. Irritation – eye

TEST SUBSTANCE Notified polymer (>98%)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White

Number of Animals	3 Males, 3 Females
Observation Period	48 hours
Remarks - Method	0.1 mL of the test substance (undiluted) was administered into the right eye of 6 animals. The study was terminated after the 48-hour observation due to severe ocular reactions.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	3	3	48 h	3
Conjunctiva: chemosis	4	4	48 h	4
Conjunctiva: discharge	3	3	48 h	3
Corneal opacity	2.7**, 3.5***	4	48 h	4
Iridial inflammation	1****	1	>24 h	1

*Calculated on the basis of the scores at 24, and 48 hours for ALL animals.
** Excessive chemosis in 3 animals prohibited scoring at 24 hours
*** Excessive chemosis in 4 animals prohibited scoring at 48 hours
**** Excessive corneal opacity in 2 animals and excessive chemosis in 3 animals prohibited scoring at 24 hours

Remarks - Results	The notified polymer caused severe reactions in the cornea, iris and conjunctiva with severe chemosis and corneal opacity preventing scoring of the cornea and iris in some animals within 48 hours. Due to the severe nature of the effects, the test was terminated after 48 hours.

CONCLUSION The notified polymer is severely irritating to the eye.

TEST FACILITY Pharmakon (1992c)

A.5. Genotoxicity – bacteria

TEST SUBSTANCE Notified polymer (>98%)

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. NIER Public Notice No. 1998-41, National Institute of Environmental Research, Korea December 23, 1998. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100. *E. coli*: WP2uvrA
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 0, 25, 50, 100, 200, 400µg/plate. b) Without metabolic activation: 0, 25, 50, 100, 200, 400µg/plate.
Vehicle	DMSO
Remarks - Method	No significant protocol deviations. Dose levels for the main study were determined by a preliminary range-finding study using the following concentrations: 0, 8, 40, 200, 1000 and 5000 µg/plate in the presence and absence of metabolic activation in the TA100 and TA 98 strains. Toxicity was observed at concentrations > 1000 µg/plate in TA100 and >40 µg/plate in TA98. Therefore, the concentrations used in the main study were: 25, 50, 100, 200 and 400 µg/plate.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	200 µg/plate	200 µg/plate	Not reported	negative
Test 2	Not performed	200 µg/plate	Not reported	negative

Present				
Test 1	200 µg/plate	400 µg/plate	Not reported	negative
Test 2	Not performed	400 µg/plate	Not reported	negative

Remarks - Results: Reduced growth of the background lawn was observed in several strains at 400 µg/plate in the absence of metabolic activation and in the TA1535 strain in the presence of metabolic activation.

All the positive control chemicals used in the test (Sodium Azide, 4-Nitroquinoline-1-oxide, 9-Aminoacridine and 2-Aminoanthracene) induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION: The notified polymer was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Korea Research Institute of Chemical Technology (1999a).

A.6. Genotoxicity – in vitro

TEST SUBSTANCE: Notified polymer (>98%)

METHOD: OECD TG 473 In vitro Mammalian Chromosome Aberration Test.
In vitro chromosome aberration test using cultured Chinese Hamster Lung (CHL) cells
NIER Public Notice No. 1998-41, National Institute of Environmental Research, Korea December 23, 1998.

Species/Strain: Chinese hamster
Cell Type/Cell Line: Lung cells
Metabolic Activation System: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Vehicle: DMSO
Remarks - Method: No significant protocol deviations. A preliminary range-finding study was done to determine the maximum dose levels for the main study.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 0.6*, 1.2*, 2.4*	6 h	24 h
Test 2	0*, 0.4*, 0.8*, 1.6*	24 h	24 h
Present			
Test 1	0*, 8*, 16*, 32*	3 h	24 h
	0, 8*, 16*, 32*	3 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	N/A	>2.4	Not reported	negative
Test 2	N/A	>1.6	Not reported	negative
Present				
Test 1	N/A	>32	Not reported	negative
Test 2	N/A	>32	Not reported	negative

Remarks - Results: There was no statistically significant increase in the number of aberrant metaphases, having structural and/or numerical aberrations, in any of the

	treated cell groups. There was a statistically significant increase in the number of aberrant metaphase with polyploids and endoreduplications in the cells treated with 2.4 μg/mL for 6 hrs in the absence of metabolic activation. However there was no dose response and the frequency was very low suggesting no biological significance. Precipitation or cytotoxicity as measured by a decrease in mitotic index was not reported. No biologically significant increase in the frequency of chromosomal aberrations or polyploidy was observed at any concentration used in the presence or absence of metabolic activation. Positive controls (cyclophosphamide and ethylmethanesulfonate) were used and demonstrated significant increases in aberrant metaphases in the presence of S-9, confirming the sensitivity of the test system and the activity of the S-9 mix.
CONCLUSION	The notified polymer was not clastogenic to Chinese Hamster Lung cells treated in vitro under the conditions of the test.
TEST FACILITY	Korea Research Institute of Chemical Technology (1999b).

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1 Ready biodegradability

TEST SUBSTANCE	Notified polymer (>98%)
METHOD	Testing Guidelines for Toxicology Studies and in compliance with the Good Laboratory Practice Regulations for Nonclinical Laboratory Studies (Notification No. 1997-9, issued by the National Institute of Environmental Research, Korea on December 22, 1997)
Inoculum	Collected from 15 sites including river, domestic sewage treatment plant, industrial wastewater treatment plants etc. The samples were pooled and incubated for a month before use.
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	None
Remarks - Method	The method is similar to OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*[a]	*Day*	*% Degradation*
7	0	7	72.8
14	0	14	76.9
28	0	28	70.7

[a] Negative values calculated

Remarks - Results	The reference substance was degraded 71% by day 28, indicating a valid test. All the validation criteria for OECD TG 301 C were satisfied except the difference of the replicate BOD measurements at the end of the test was > 20% (33%). Negative oxygen uptakes and a high variation between the replicate measurements were reported. As the reference compound reached the pass level for biodegradability, the test is considered valid.
CONCLUSION	The notified polymer is considered not to be readily biodegradable
TEST FACILITY	Korea Research Institute of Chemical Technology (1998)

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