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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in Miralan HTP

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Specialty Chemicals Pty Limited (ABN. 97 005 061 469) of 235 Settlement Road, Thomastown, VIC, 3074.

NOTIFICATION CATEGORY
Standard: Polymer with NAMW < 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Identity
Polymer composition including nature of impurities
Spectral data
Detailed Use
Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Physical and chemical properties
Vapour pressure
Hydrolysis as a Function of pH
Partition Coefficient (n-octanol/water)
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Dissociation Constant
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Toxicity Data
Acute dermal toxicity
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Genotoxicity – bacterial reverse mutation
Genotoxicity – *in vitro*
Genotoxicity – *in vivo*

Ecotoxicity Data
Bioaccumulation
Acute toxicity to aquatic invertebrates
Algal growth inhibition test

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

OTHER NAME(S)
Polyalkyleneglycol maleinate

MARKETING NAME(S)
The notified polymer is not isolated and therefore does not have a marketing name. It is imported as a 70% solution with the name Miralan HTP.

METHODS OF DETECTION AND DETERMINATION

METHOD	Molecular weight determined by Negative Electrospray Ionisation Mass Spectrometry (ESI-MS) Structural confirmation by Infrared spectroscopy
Remarks	Spectra provided for Miralan HTP (containing up to 70% notified polymer)

3. COMPOSITION

DEGREE OF PURITY
> 98%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
All hazardous impurities or residual monomers are present at below the relevant cut offs for classification of the notified polymer as a hazardous substance on the basis of monomer impurity content.

DEGRADATION PRODUCTS
Over time, transesterification with the solvent occurs.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
The residual monomers may be lost to the environment when the polymer or product containing it is in the liquid state. However, residual monomer content is very low. Once the textile products are cured, the monomers will be trapped in the solid matrix

4. 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 will be imported in the form of a solution containing up to 70% of the notified polymer.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	10-30	10-30

USE
The notified polymer is used as a processing aid in the textile dyeing industry.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
The notified polymer will be imported through Victoria, by wharf.

IDENTITY OF RECIPIENTS
The notified polymer will be stored at the notifiers warehouse in Thomastown, Victoria before being supplied to a number of textile manufacturers.

TRANSPORTATION AND PACKAGING
Miralan HTP containing the notified polymer at up to 70% will be imported in 60 kg, high density plastic kegs. The plastic kegs containing the Miralan HTP will be transported by road from the wharf

to the notifiers site and thence to end-users (textile industry) warehouses.

5.2. Operation description

Formulation

At the textile finishing facility under local exhaust ventilation the plastic kegs of Miralan HTP containing up to 70% notified polymer, will be transferred on a pallet by forklift from the warehouse area to the mixing area. The plastic kegs will be placed onto scales and an automated pumping system will be used to transfer the required amount of Miralan HTP from the plastic keg to a dye blending tank. Other ingredients will also be dosed into the dye blending tank. Blending will take approximately two hours. The final concentration of the notified polymer in the dye solution is < 5%. At the end of the blending process, samples are taken via a sampling port into sampling jars for quality control.

Dyeing/curing

The dye solution is pumped through a closed system to a high temperature dyeing machine The cloth to be dyed is fed into the mechanism that passes the cloth through the dyeing machine. The dye solution is then applied to fabric by an exhaustion dyeing machine. Approximately 10% of the notified polymer in the dye solution is reported to adhere to the fabric. Following exhaust of dye on to the cloth, the wet dyed cloth will be unloaded from the dyeing machine and transferred to curing and drying ovens.

The exhaust dyeing machine and lines will be cleaned after the dyeing process by flushing the system with water. Cleaning residues will be sent to the waste water pit on site. After emptying, the plastic kegs containing the notified polymer will be collected by licensed chemical waste contractors for disposal via incineration.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	6-8	2-3 hours/day	10-15 days/year
Textile Finishing Facility			
Blending/dilution	2	3 hours/day	75 days/year
Loading drying machines	2	1 hour/day (over 3 shifts)	75 days/year
Unloading dyeing machines	2	1 hour/day (over 3 shifts)	75 days/year
Quality control	2	1 hour/day	75 days/year

Exposure Details

Transport and storage

Approximately six dockside and warehouse workers will be involved in transporting Miralan HTP from wharf to the Ciba warehousing facility. A further two warehouse workers will be involved in transferring the plastic kegs from Ciba Warehousing facility to the textile industry warehouses. Dockside and warehouse workers routinely wear cotton overalls and steel-caped boots. They are not expected to have any contact with the notified polymer, except in case of an accident.

Formulation

Two process operators will be involved in formulation of the dye solution. One of these operators will be responsible for transporting Miralan HTP from the warehouse to the blending area, and transferring the required amount of Miralan HTP via an automated pumping system into a closed exhaust dying machine.

There is expected to be no exposure to the notified polymer when it is transferred from the plastic keg to the dyeing machine because this is a fully automated process which is also carried out under local exhaust ventilation.

Exposure to the notified polymer is not expected during blending, as this is an automated process and occurs in a closed vessel. Exposure to the polymer is not expected during the cleaning of equipment as the machine is self-cleaning and is fully automated. As a precaution process operators will wear elbow length PVC gloves, cotton overalls, safety goggles and safety boots.

Dyeing – Loading Dyeing Machine
Two workers are involved in loading dyeing machines. Workers involved with feeding fabric into the dyeing machine may be exposed to the dye solution (containing < 5% of the notified polymer) in the event of a tangle in the dyeing machine. In such an event, it may be necessary to let the machine cool and then open it to remove the tangle.

Workers will wear tightly fitting safety goggles, chemical resistant protective gloves and overalls to minimise any exposure.

Dyeing-Unloading Dyeing Machine
Workers handling the wet dyed cloth during unloading of the dyeing machine and transfer to the curing and drying ovens may be exposed to the notified polymer at a worst case concentration of 5%. Although it is stated that only approximately 10% of the notified polymer in the dye solution adheres to the fabric, as no supporting data was provided it is assumed that all the notified polymer is transferred with the dye.

The handling of undried fabric is carried out under local exhaust ventilation to prevent inhalation exposure. Workers will wear tightly fitting safety goggles, chemical resistant protective gloves and overalls to minimise any exposure.

Drying
Textiles treated with the notified polymer will be cured in drying ovens. During curing, no harmful degradation products are expected to be released. The notified polymer will be present at a worst case concentration of 5% when it is applied to textiles. The drying ovens will be fitted with forced ventilation.

There is expected to be negligible exposure for workers handling dry textiles, as the polymer will be bound to the textile fibres

Quality Control
Dermal and ocular exposure to the notified polymer at a concentration of < 5% may occur during sampling of the dye solution. However, QC officers will only be handling very small quantities of the dye solution. As a precaution QC workers will wear goggles, chemical resistant protective gloves and laboratory coats to prevent exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Environmental release of the notified polymer is unlikely during importation, storage and transportation, and accidental spills, leaks and catastrophic mechanical failure during a transport accident are the most likely reasons for environmental release. Engineering controls (eg. drum specifications) and emergency clean-up procedures (ie. spill response instructions on Safety Data Sheet and label) will limit the impact on the environment of such incidents. Containers holding the notified polymer will be transported directly from the Port facility to manufacturing facilities in Australia for storage prior to blending and application to textile products.

Releases during blending and textile application are not expected due to the automated and enclosed equipment used during these activities. Emptied imported containers will be rinsed (water), with rinsate blended into subsequent batches. Cleaning of blending equipment and exhaust dyeing apparatus with water will result in the generation of wastewater containing a small quantity of the notified polymer.

RELEASE OF CHEMICAL FROM USE

An unspecified proportion of the notified polymer in the dye mixture is expected to fix to textile fibre, and spent dyeing liquids will be disposed of as wastewater. Wastewater will be sent to sewer after on-site wastewater treatment involving solids collection and sludge aggregation. Sludge, which may potentially contain a small quantity of the notified polymer, will be incinerated or sent to landfill for disposal.

Leaching of the notified polymer from treated textiles, such as from washing, is not expected by the notifier as after curing it will be tightly bound; however, any residual leached is likely to go to sewer where treatment will occur. The use pattern will be diverse and widespread throughout Australia.

5.5. Disposal

Spent dyeing solution, containing an unspecified concentration of notified polymer, will be sent to sewer after onsite wastewater treatment. Emptied imported containers will be rinsed and reused, metal recycled or sent to landfill for disposal. Spilled material, estimated to comprise 1% of the import quantity of the notified polymer, will be collected by licensed waste contractor for disposal by incineration. At the end of life, treated waste textiles will be sent to landfill for disposal. Disposal of textile products will be widespread throughout Australia.

5.6. Public exposure

The notified polymer and products containing it are not available for sale to the public. Members of the public will make dermal contact with the dried form of the notified polymer when handling treated textiles, the notified polymer will be present in the textile at a worst case concentration of 5% and it is expected to be tightly bound to the textile.

The potential for public exposure to the notified polymer during transport, application to textile or disposal is negligible.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer is not isolated and therefore physico-chemical data for the notified polymer is not available. Some physicochemical properties have been supplied for Miralan HTP (a 70% solvent solution of the notified polymer).

Appearance at 20ºC and 101.3 kPa	Clear light yellow liquid with characteristic odour (Miralan HTP)
Melting Point	Not determined
Remarks	The notified polymer will only be introduced and used as a solution
Boiling Point	> 200ºC at 101.3 kPa (Miralan HTP)
Remarks	Taken from MSDS (Ciba Specialty Chemicals, 2003). No study report provided.
Density	1200 kg/m^3 at 20ºC (Miralan HTP)
Remarks	Taken from MSDS (Ciba Specialty Chemicals, 2003). No study report provided.
Vapour Pressure	Not determined
Remarks	Based on the relatively high boiling point of Miralan HTP, the vapour pressure is expected to be low. Polymers consist of a range of different species. Using MPBPWIN v1.40 QSAR software (modified grain method), a vapour pressure of $7.06X10^{-14}$ mmHg has been estimated for one species of the notified polymer.
Water Solubility	> 50g/L at 25ºC (Miralan HTP)
Remarks	Data taken from Ciba data sheet. No study provided.

The presence of solvents (30%) in Miralan HTP can affect the relevance of this test. Based on the notified polymers structure the notified polymer is expected to be water soluble.

Polymers consist of a range of different species having different molecular weights and hence different water solubilities. Using WSKOW v1.40 QSAR computer software, a water solubility of 5.3 g/L at 25°C has been estimated for one species based on an estimated low Kow of -0.72 (see below).

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer contains ester groups which may undergo hydrolysis. Using HYDROWIN v1.67 QSAR computer software, the half-life of one species of the notified polymer in water at pH 7 and pH 8 (at 25°C) is estimated to be 8.6 days and 86 days, respectively.

Partition Coefficient (n-octanol/water) Not determined

Remarks Polymers consist of a range of different species. The Log K_{OW} has been estimated for two different species of the notified polymer as follows (the software used for the estimation has been included in brackets):
log Kow = -0.38 (ACD computer software)
log Kow = -0.72 (LOGKOW QSAR computer software)

Adsorption/Desorption Not determined
– screening test

Remarks Polymers consist of a range of different species. The Log K_{OC} has been estimated for two different species of the notified polymer as follows (the software used for the estimation has been included in brackets):
Log Koc = 1.2 (ACD computer software)
Log Koc = -2.07 (PCKOCWIN v1.66 QSAR computer software)

The notified polymer has an affinity to the aqueous phase and will be mobile. During the inherent biodegradability test, ~0.3% of the notified polymer was adsorbed to solids.

Dissociation Constant Not determined

Remarks The notified polymer contains the maleic acid moiety. The pKa_1 of maleic acid is 1.94 at 25°C (European Chemicals Bureau, 2000)

Particle Size Not determined

Remarks The notified polymer is not isolated from solution

Viscosity 1500-4000 mPa at 20°C

Remarks Data taken from Ciba data sheet. No study provided.

Flash Point > 100°C (Miralan HTP)

Remarks Taken from MSDS (Ciba Specialty Chemicals, 2003). No study report provided.

Flammability Limits Not determined

Remarks The notified polymer is not expected to be flammable.

Autoignition Temperature Not determined

Remarks The notified polymer is not expected to autoignite.

Explosive Properties Not predicted to be explosive

Remarks From examination of the structure, there are no chemical groups that would infer explosive properties, therefore, the notified polymer is regarded as non-explosive.

Reactivity

Remarks Over time, transesterification with the solvent occurs.

7. TOXICOLOGICAL INVESTIGATIONS

Acute oral toxicity, skin irritation and eye irritation data was submitted for Miralan HTP (70% solution of the notified polymer). Data for the other toxicological end points with the exception of sensitisation was taken from the IUCLID Data Set for Maleic acid (European Chemicals Bureau, 2000) or associated references. Data for sensitisation was taken from a meeting Agenda for the European commission working group on the Classification and Labelling of Dangerous Substances (European Chemicals Bureau, 2004)
Maleic acid was considered to be a suitable analogue because the maleic acid portion of the notified polymer is predicted to dictate the toxicology profile of the notified polymer. Furthermore, the notified polymer is expected to hydrolyse in biological systems to form maleic acid and the corresponding glycols.

Endpoint and Result	*Test Substance*	*Assessment Conclusion*
Rat, acute oral	Miralan HTP	low toxicity, LD50 > 2000 mg/kg bw
Rabbit, acute dermal	Maleic acid	Harmful, LD50 1560 mg/kg bw
Rat, acute inhalation	Maleic acid	not possible to classify, LC50 > 0.72 mg/L/hour
Rabbit, skin irritation	Miralan HTP	slightly irritating
Rabbit, eye irritation	Miralan HTP	irritating
Guinea pig, skin sensitisation – adjuvant test	Maleic acid	evidence of sensitisation.
Skin sensitisation – mouse local lymph node assay (LLNA)	Maleic acid	evidence of sensitisation.
Rat, repeat dose oral toxicity – 28 days.	Maleic acid	Not possible to establish a NOAEL
Rat, repeat dose oral toxicity – 53 days.	Maleic acid	Not possible to establish a NOAEL
Genotoxicity – bacterial reverse mutation	Maleic acid	non mutagenic
Genotoxicity – in vitro DNA synthesis inhibition test.	Maleic acid	genotoxic
Genotoxicity – in vitro Vicia root tip micronucleus assay	Maleic acid	non genotoxic
Carcinogenicity, 2 year oral study in rats	Maleic acid	No evidence of carcinogenicity. NOAEL (general toxicity) < 250 mg/kg bw/day

7.1. Acute toxicity – oral

TEST SUBSTANCE Miralan HTP

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.

Species/Strain Rat/Albino (Tif: RAI f (SPF))
Vehicle 0.5% (w/v) carboxymethylcellulose in 0.1% (w/v) aqueous polysorbate 80.
Remarks – Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2000 mg/kg bw	0/10

LD50 > 2000 mg/kg bw
Signs of Toxicity Piloerection, hunched posture, and dyspnea were observed in both male and female animals. All animals recovered by day two. Body weight was

	not affected by treatment.
Effects in Organs	No abnormalities were observed.
Remarks – Results	The dose refers level refers to Miralan HTP, this corresponds to a dose of 1400 mg/kg bw for the notified polymer. The solvent in Miralan HTP is of low acute oral toxicity and therefore is not considered to impact the study.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	Ciba-Giegy (1995a)

7.2. Acute toxicity – dermal

TEST SUBSTANCE	Maleic acid
Remarks - Method	Acute dermal toxicity data was provided for two animals. No details of the methods used were provided.

RESULTS

Species	*Results*
Rabbit	LD50 = 1560 mg/kg bw
Guinea pig	LD50 > 1000 mg/kg bw

Remarks - Results	No details of signs of toxicity or effects in organs were provided
CONCLUSION	The test substance is harmful via the dermal route.
TEST FACILITY	European Chemicals Bureau (2000)

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	Maleic acid
METHOD	
Species/Strain	Rat
Exposure Period	1 hour
Remarks - Method	The summary of one acute inhalation toxicity study was provided. Other than the exposure period no details of the method used was provided.

RESULTS

LC50	> 0.72 mg/L/hour
Remarks - Results	No details of signs of toxicity or effects in organs were provided
CONCLUSION	Due to the low dose and exposure time it is not possible to classify the toxicity of the test substance via inhalation.
TEST FACILITY	European Chemicals Bureau (2000)

7.4. Irritation – skin

TEST SUBSTANCE	Miralan HTP
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion. EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
Species/Strain	Rabbit/New Zealand White

Number of Animals	3 female
Vehicle	None; test substance as supplied
Observation Period	7 days
Type of Dressing	Semi-occlusive.
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0.33	1	0.33	1	72 hours	0
Oedema	0.33	0.33	0	1	24 hours	0

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

Remarks - Results	Very slight erythema and very slight oedema was observed in all animals on the day of application. The erythema persisted in one animal up to 72 hours after application. All signs of irritation had reversed by day 7. The solvent in Miralan HTP was observed to be slightly irritating in studies. Therefore the presence of the solvent may be influencing the observed result in this study.
CONCLUSION	The notified polymer is slightly irritating to the skin.
TEST FACILITY	Ciba-Geigy (1995b)

7.5. Irritation – eye

TEST SUBSTANCE	Miralan HTP
METHOD	OECD TG 405 Acute Eye Irritation/Corrosion. EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 male
Observation Period	14 days
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	2.33	3	3	10 days	0
Conjunctiva: chemosis	1.67	2.33	2.33	3	7 days	0
Conjunctiva: discharge						
Corneal opacity	1	1	1	1	10 days	0
Iridial inflammation	1	1	1	1	72 hours	0

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

Remarks - Results	Irritation of the cornea, iris and conjunctiva was observed in all animals. A whitish discolouration of the conjunctiva was seen in two animals up to 72 hours. A slight bulging of the cornea was seen in one animal only on day seven of the study. All signs of irritation were reversed within 14 days. The solvent in Miralan HTP was found to be non-irritating to eyes in a number of studies and therefore is not considered to impact the result of

this study.

CONCLUSION The notified polymer is irritating to the eye.

TEST FACILITY Ciba-Geigy (1995c)

7.6.1 Skin sensitisation – maximisation test

TEST SUBSTANCE Maleic acid

METHOD OECD TG 406 Skin Sensitisation – maximisation test
EC Directive 96/54/EC B.6 Skin Sensitisation - maximisation test.

Species/Strain Guinea pig

PRELIMINARY STUDY Conducted but no details provided

MAIN STUDY

Number of Animals Test Group: 10 Control Group: 5

INDUCTION PHASE Induction Concentration:
intradermal: 1% in physiological saline
topical: 35% in deionised water

Signs of Irritation Both the control and test group animals had severe erythema and/or oedema after the topical induction stage. These effects were attributed to the adjuvant.

CHALLENGE PHASE

1st challenge topical: 25% in deionised water

2nd challenge topical: 1% in deionised water

Remarks - Method Full study report not reviewed.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	25%	10/10	Not provided	N/A	N/A
	1%	N/A	N/A	3/10	3/10
Control Group	25%	5/5	Not provided	N/A	N/A
	1%	N/A	N/A	0/5	0/5

Remarks - Results After the first challenge both control and test group animals showed severe erythema and/or oedema accompanied by eschar. All skin reactions were regarded as mainly irritative. Following the second challenge 3/10 test animals had severe erythema and/or oedema 24 and 48 hours after exposure. No adverse skin reactions were observed in control animals.

CONCLUSION There was evidence of reactions indicative of skin sensitisation to the test substance under the conditions of the test.

TEST FACILITY European Chemicals Bureau (2004)

7.6.2 Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Maleic acid

METHOD

Species/Strain Mouse

Vehicle	N,N-Dimethylformamide
Remarks - Method	Full study report not reviewed.

RESULTS

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	Not provided	Not provided
1	Not provided	11.2
2.5	Not provided	22.
5	Not provided	31.5
Positive Control		
25% hexyl cinnamic aldehyde in acetone:olive oil (4:1)	Not provided	14.6

Remarks - Results	Moderate erythema was observed in all high dose (5%) group animals on day 2 and in a few animals in all test groups on day 3. Statistically significant difference of the mean ear thickness in the mid hand high dose test animals compared to the negative control group confirmed these effects. As the positive result (SI> 3) in the low dose test animals was not accompanied by increased ear thickness and excessive local irritation, false positive results can be excluded.
CONCLUSION	There was evidence of a lymphocyte proliferative response indicative of skin sensitisation to the test substance.
TEST FACILITY	European Chemicals Bureau (2004)

7.7.1 28 day Repeat dose oral toxicity (rat)

TEST SUBSTANCE	Maleic acid

METHOD

Species/Strain	Rat
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: None
Vehicle	Feed
Remarks - Method	Only a summary of the study was reviewed. Other than information provided above, no details of the method used was provided.

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration ppm*		*Mortality*
		Nominal	*Actual*	
I (control)	Not provided	0	0	Not recorded
II (low dose)	Not provided	300	Not provided	Not recorded
III (mid dose)	Not provided	1000	Not provided	Not recorded
IV (high dose)	Not provided	3250	Not provided	1

Mortality and Time to Death
One rat died in the highest dose groups on day 8; cause of death was not determined.

Clinical Observations
Slight reduced weight gain (unspecified) in high dose animals was recorded.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
No details provided.

Effects in Organs
There was a statistically significant difference (unspecified) in relative adrenal weight in all dose groups compared to the control group. There was no difference in relative liver, kidney and testes weight.

Remarks – Results
Other than the information above, no detailed results were provided. Test data has not been reviewed.

CONCLUSION
Due to insufficient information, it is not possible to establish a No Observed Adverse Effect Level (NOAEL) in this study.

TEST FACILITY European Chemicals Bureau (2000)

7.7.2 53 day Repeat dose oral toxicity (rat)

TEST SUBSTANCE Maleic acid

METHOD

Species/Strain	Rat
Route of Administration	subcutaneous injection
Exposure Information	Total exposure days: up to 53 days; Dose regimen: 7 days per week; Post-exposure observation period: None
Vehicle	Sesame Oil
Remarks - Method	Each rat was started at the age of 7 days. The dose was increased from 0.1 to 2.0 mg/day/rat. Only a summary of the study was reviewed. Other than information provided above, no details of the method used was provided

RESULTS

Remarks – Results
The average weight, length and rate of development of the injected rats showed no significant variations compared to the control.

Other than the information above, no detailed results were provided. Test data has not been reviewed.

CONCLUSION
Due to insufficient information it is not possible to establish a No Observed Adverse Effect Level (NOAEL) in this study.

TEST FACILITY European Chemicals Bureau (2000)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Maleic acid

METHOD & RESULTS

Remarks - Method The following information was provided for five bacterial mutation assays. Only a summary of these studies was reviewed. Other than information provided below, no details of the method used was provided

Method	*Species/Strain*	*Metabolic activation*	*Result*
not provided	not provided	with and without	negative
not provided	*Salmonella typhimurium* TA 100	no data	negative
not provided	*Escherichia coli* Sd-4-73	no data	negative
Not provided	*Salmonella typhimurium* TA1535, TA1537, TA1538, TA98, TA100	with and without	negative
preincubation method	*Salmonella typhimurium* TA97, TA98, TA100, TA102, TA104	with and without	negative

Remarks - Results Other than the information above, no detailed results were provided. Test data has not been reviewed.

CONCLUSION The test substance was not mutagenic to bacteria under the conditions of these tests.

TEST FACILITY European Chemicals Bureau (2000)

7.9.1 Genotoxicity – in vitro DNA synthesis inhibition test

TEST SUBSTANCE Maleic Acid

METHOD

Cell Type/Cell Line Human Fibroblasts, YH-1 cells
Metabolic Activation System Polychlorinated biphenyl induced rat liver S9 fraction
Vehicle Eagle's minimum essential medium (MEM) supplemented with 10% fetal calf serum.
Remarks - Method Basic method details are as follows:
The cells were labelled overnight with [2-^{14}C]thymidine. The following day the cell were exposed to media containing maleic acid with S9 mixture for 30 minutes and then washed with fresh medium. At 30, 90 and 150 minutes after washing, the cells were pulse-labelled for 10 minutes with [6-^{3}H]thymidine, then harvested and counted. The relative rate of DNA synthesis (unspecified number of replications) was calculated from the ^{3}H/^{14}C ratio of the culture exposed to a maleic acid divided by that of the unexposed culture pulse-labelled at the same time. Control wells were treated in the same way as the treated cells except the

cells were exposed to [4,5-^{3}H]leucine. The relative rate of protein synthesis was calculated in the same way as for DNA synthesis and used to confirm that the results of DNA synthesis were due neither to cell damage nor inhibition of protein synthesis.

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	-	-	-
Test 2	-	-	-
Present			
Test 1	2320	30 mins	1 hr, 2hr, 3hr
Test 2	-	-	-

*Cultures selected for metaphase analysis.

RESULTS

Remarks - Results: An inhibition of DNA synthesis (~50%) was observed at 90 minutes from the end of the exposure period. The rate of synthesis then increased again to close to control value by 150 minutes from the end of the exposure period.

CONCLUSION: The notified polymer was clastogenic to human fibroblasts treated in vitro under the conditions of the test.

TEST FACILITY: Yanagisawa et al (1987)

7.9.2 Genotoxicity – in vitro Vicia root tip micronucleus assay

TEST SUBSTANCE: Maleic acid

METHOD & RESULTS

Remarks - Method: The following information was provided for the following in vitro genotoxicity study

Method	*System of testing*	*Metabolic activation*	*Result*
vicia root tip micronucleus assay for clastogenicity	primary root tips of Vicia faba	no data	negative

Remarks - Results: Other than the information above, no detailed results were provided. Test data has not been reviewed.

CONCLUSION: The test substance was not clastogenic to vicia root tip cells treated in vitro under the conditions of the test.

TEST FACILITY: European Chemicals Bureau (2000)

7.10. Genotoxicity – in vivo

No data submitted.

7.11 Chronic toxicity/carcinogenicity 2 year study (rat)

TEST SUBSTANCE: Maleic acid

METHOD

Species/Strain	Rat
Route of Administration	Oral –diet
Exposure Information	Total exposure days: 2 years; Dose regimen: 7 days per week;
Vehicle	Feed
Remarks - Method	Only a summary of the study was reviewed. Other than information provided above, no details of the method used was provided

RESULTS

Group	*Number and Sex of Animals*	*Dose/Concentration*		*Mortality (at 2 years)*
		Nominal (%)	*Actual (approx) mg/kg bw*	
I (control)	12 male	0	0	6/12
II (low dose)	12 male	0.5	250	10/12
III (mid dose)	12 male	1.0	500	10/12
IV (high dose)	12 male	1.5	750	12/12

Mortality and Time to Death

Most of the deaths occurred during the second year of the experiment. At eighteen months the mortality rate in the mid and high dose animals had increased (unspecified) but not significantly. At two years the maleic acid had increased the mortality rate significantly.

Clinical Observations

Bodyweight gain in the first 52 weeks of the study were significantly reduced in the mid ($P < 0.05$) and high ($P < 0.001$) dose group animals by approximately 20 and 40% respectively, compared to controls. No significant differences in feed consumption were noted.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

No details provided.

Effects in Organs – General

Enlarged and irregularly shaped epithelial cells in small to moderate numbers of renal tubules (generally in the proximal convoluted tubules), were seen in Group III (3 of 12) and Group IV (4 of 12) rats.

Increased (unspecified) atrophy of the liver and testis and less focal calcification in large arteries was reported in Group IV rats.

Effects in Organs – Tumours

No tumorigenisis was reported

Remarks – Results

Other than the information above, no detailed results were provided. Test data has not been reviewed.

The dose administered to Group II, III and IV animals was approximately 5%, 70% and 94% respectively of the reported oral LD50 value for maleic acid of 708 mg/kg bw (European Chemicals Bureau, 2000)

CONCLUSION

There was no evidence of carginogenicity. Due to excess mortality observed in all dose groups it is not possible to establish a No Observed Adverse Effect Level (NOAEL) in this study. The NOAEL in male rats would be < 250mg/kg bw.

TEST FACILITY Fitzhugh et al (1947), European Chemicals Bureau (2000)

8. ENVIRONMENT

Limited data have been provided for Miralan HTP (70% solution of the notified polymer). This was mainly in the form of a laboratory sheets and result tables (some in German).

8.1. Environmental fate

8.1.1. Inherent biodegradability

TEST SUBSTANCE Miralan HTP

METHOD OECD 302B Modified Zahn-Wellens Test
Exposure Period 12 days
Remarks - Method Full test method not provided. Determined by measurement of % DOC elimination.

RESULTS

Test substance (309 mg/L)		*Reference Substance (not specified)*	
Day	*% Degradation*	*Day*	*% Degradation*
1	4.8	1	2.4
2	18.3	2	6.9
5	66.8	5	99.9
6	78.6	6	98.7
7	84.4	7	-
9	95.5	9	-
12	94.3	12	-

Remarks - Results Full test results not provided.

CONCLUSION The test material achieved ~94% biodegradation within 12 days. Absorption to solids accounted for only 0.3% of the notified polymer. Caution in advised in interpretation of results given the paucity of information provided.

TEST FACILITY Not stated (1995 study, in German).

8.1.2. Bioaccumulation Not determined

Remarks A bioconcentration factor (BCF) of ~1 has been estimated using ACD computer software (estimated) based on a component. The high water solubility and low BCF indicate that the notified polymer is unlikely to bioaccumulate in aquatic organisms.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Miralan HTP

METHOD OECD 203 Acute Fish Toxicity Test (test conditions not provided).
Species Zebra fish
Exposure Period 96 hours
Remarks – Method Full test method not provided. Test pH range 8.4-8.5; Dissolved oxygen 91-95% saturation; Temp: 23°C (acceptable).

RESULTS
LC50 > 300 mg/L at 96 hours.
NOEC 300 mg/L at 96 hours

CONCLUSION	The limited data presented indicate that the formulation tested containing the notified polymer is practically non-toxic to fish, ie. L(E)C50 > 100 mg/L). Caution in advised in interpretation of results given the paucity of information provided.
TEST FACILITY	Material Safety Data Sheet (Ciba Specialty Chemicals, 2003).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Miralan HTP
METHOD	OECD 209
Inoculum	
Exposure Period	3 h
Concentration Range	20, 64, 200, 640 mg/L
Remarks – Method	Full test method not provided. Test reference 3, 5-dichlorophenol.
RESULTS	
IC50	> 640 mg/L at 3 h
Remarks – Results	The reference toxicant had a 3 h IC50 of 14 mg/L.
CONCLUSION	The limited data presented indicate that the formulation tested containing the notified polymer is practically non-inhibitory to sewage micro-organisms. Caution in advised in interpretation of results given the paucity of information provided.
TEST FACILITY	Material Safety Data Sheet (Ciba Specialty Chemicals, 2003; Ciba Geigy, 1995d).

Additional Ecotoxicity Data

Using the USEPA QSAR computer software, ECOSAR, the following estimates for ecotoxicity have been derived for one species of the notified polymer. (Input parameters were acid moiety, Log Kow of -0.72 and water solubility of $1.4x10^3$ g/L).

ORGANISM	ENDPOINT	PREDICTED ECOTOXICITY (mg/L)
Fish	96 h LC50	244
Daphnia	48 h LC50	12449
Green algae	96 h EC50	1124

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer has a low estimated vapour pressure and atmospheric losses are not expected to be significant. With an expected high water solubility and low affinity to organic carbon and lipids, the notified polymer is likely to partition to the water phase and not absorb to suspended solids, sediments or bioaccumulate in aquatic organisms. In the environment, landfill or sewer, the notified polymer is expected to biodegrade over time given the high clearance (~94% in 12 days) under inherent biodegradability test conditions. Incineration of wastes will destroy the notified polymer and result in the formation of oxides of carbon and water.

The majority of the notified polymer will be discarded to sewer in spent dye solution after use. The Australian wool textile manufacturing industry is based mainly (> 90%) in Victoria (~54%) and New South Wales (~38%), with smaller operations in other States (~8% in Western Australia and Queensland; (IBISWorld, 2004, http:www.ibisworld.com.au). New South Wales and Victoria treat ~65% (ASTE, 2004) of Australia's wastewater (~2.6 x 10^9 L/day or 9.5x10^{11} L/year). This assumes a national wastewater generation rate of ~4.02x10^9 L/day (based on 20.1 million people generating 200 L/person/day; Environment Australia, 2003).

Following discharge to sewer, the notified polymer would disperse and dilute within the sewerage system as well as undergo biodegradation. Assuming all of the import volume of the notified polymer (< 30 tonnes/year) was discharged to the New South Wales and Victorian sewerage system, the average sewer concentration of the notified polymer may potentially approximate 0.032 mg/L. Under conditions of no biodegradation of the notified polymer and assuming dilution factors for freshwater and marine environments of 1 and 10, respectively, a predicted environmental concentration (PEC) (freshwater) and PEC (marine) of 0.032 and 0.0032 mg/L has been derived.

In addition to dilution, biodegradation of the notified polymer is expected to occur within the sewerage system thereby reducing these estimated exposure concentrations further. The SimpleTreat 3.0 model (Struijs *et al*., 1996; European Chemicals Bureau, 2003) with averaged or assumed parameters for molecular weight, vapour pressure and water solubility, and assuming inherent biodegradability has been used to estimate partitioning of the notified polymer within a sewerage treatment plant with biological treatment. With input parameters of inherent biodegradability, log Kow of -0.38, log H of -6.2, vapour pressure of 0.0001 Pa and water solubility of 50 g/L, the SimpleTreat model indicates that ~40% of the load of the notified polymer may be biodegraded, and a sewerage system effluent concentration of ~0.02 mg/L has been estimated. Predicted environmental concentrations (PECs) for freshwater and marine outfall discharges of 0.02 mg/L and 0.002 mg/L have been derived based on dilution factors of 1 and 10, respectively.

9.1.2. Environment – effects assessment

A formulation containing the notified polymer is practically non-toxic to zebrafish during a 96 hour exposure period and did not inhibit sewage microbes exposed over a 3 hour period. A predicted no effect concentration (PNEC) of > 0.3 mg/L has been derived by dividing the lowest LC50 value of > 300 mg/L by an assessment (safety) factor of 1000, to account for the paucity of aquatic toxicity data available.

9.1.3. Environment – risk characterisation

A hazard quotient (HQ) approach has been used to assess risks to aquatic organisms where HQ = PEC ÷ PNEC. In the absence of biodegradation of the notified polymer, HQ values for freshwater and marine waters of < 0.1 (ie. 0.032 ÷ > 0.3) and < 0.01 (ie. 0.0032 ÷ > 0.3) have been derived. However, assuming mitigation through biodegradation, HQ values for freshwater and marine ecosystem of < 0.07 (ie. 0.02 ÷ > 0.3) and < 0.007 (ie. 0.002 ÷ > 0.3) have been derived indicating low risk to the aquatic environment. The notified polymer is not expected to bioaccumulate in aquatic organisms and is expected to biodegrade in natural systems and landfills over time.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and Storage

Exposure to the notified polymer is expected to be negligible except in the case of an accidental spill.

Formulation

Exposure to the notified polymer during formulation (including transfer and cleaning processes) of the dye solution is expected to be negligible due to the automated nature of the process. In the event of a machine malfunction, exposure to the notified polymer will still be limited due to the use of Personal Protective Equipment (PPE).

Dyeing-Loading Dyeing Machine

Incidental exposure to up to 5% notified polymer could occur while trying to untangle fabric from the machine. However, exposure to the notified polymer is expected to be low due to the low concentration, the expected low frequency of exposure and the use of PPE.

Dyeing-Unloading Dyeing Machine

Exposure to up to 5% notified polymer could occur during the transfer of the wet cloth from the dye machines to the drying ovens. The estimated dermal exposure during transfer is 0.005 - 0.05 mg/cm^2/day, based on EASE model (EASE) and assuming the notified polymer is present at concentration of 5%. Therefore, for a 70 kg worker with surface area for hands at 820 cm^2 and forearms at 1140 cm^2 and a 100% dermal absorption factor, systemic exposure is estimated to be 0.14 -1.4 mg/kg bw/day.

This estimate assumes that all the notified polymer is transferred with the dye and it does not take into account the expected low frequency of exposure and use of PPE. Taking these factors into account, the lower limit (0.14 mg/kg bw/day) should be used as the exposure value.

Drying

Following drying of the textiles, worker exposure to the notified polymer is expected to be negligible as the polymer will be bound to the textile fibres and as such will not be bioavailable.

Quality Control

Dermal and ocular exposure to the notified polymer could occur during sampling and analysis of the dye solution. However, exposure is expected to be low due to the low concentration, the expected low frequency of exposure, the small quantities involved and the use of PPE.

9.2.2. Public health – exposure assessment

Members of the public will handle and wear textile products treated with the notified polymer. The low concentration of notified polymer transferred with the dye is expected to be tightly bound within the textile and as such will not be bioavailable. Public exposure to the notified polymer is expected to be negligible.

9.2.3. Human health – effects assessment

Acute oral toxicity, skin irritation and eye irritation data was submitted for Miralan HTP which contains up to 70% notified polymer. Maleic acid was accepted as an analogue for the other toxicological end points. Maleic acid was considered to be a suitable analogue because the maleic acid portion of the notified polymer is predicted to dictate the toxicology profile of the notified polymer. Furthermore, the notified polymer is expected to hydrolyse in biological systems to form maleic acid and the corresponding glycols.

Toxicokinetics, metabolism and distribution.

Maleic acid induces kidney disfunction analogous to the human Fanconi syndrome (Cragg, 2001). Fanconi syndrome is characterized by increased urinary elimination of glucose, amino acids, and other biochemicals resulting from impaired tubular reabsorption of such materials.

A similar impact on kidney function by the notified polymer cannot be discounted.

Acute toxicity.
Based on an acute oral toxicity study conducted on a 70% solution of the notified polymer, the notified polymer is considered to be of low acute oral toxicity. No dermal toxicity study had been conducted on the notified polymer. Although maleic acid is classified as harmful on contact with skin, it is likely that the notified polymer would be of low acute dermal toxicity based on the oral toxicity results. No inhalation toxicity study had been conducted on the notified polymer and limited data was available for maleic acid. However, due to the predicted low vapour pressure, the form of the notified polymer (solution) and the low acute oral toxicity of the notified polymer, it is unlikely that atmospheric concentrations of the notified polymer would be high enough to cause an adverse effect in humans

Irritation and Sensitisation.
Based on a skin and eye irritation study conducted on a 70% solution of the notified polymer, the notified polymer is considered to be slightly irritating to skin and irritating to the eye.

Maleic acid showed evidence of sensitisation in an adjuvant test in guinea pigs and a mouse local lymph node assay. A compound of this class dibutylmaleinate is reported to show a strong sensitising effect on guinea pig skin (SIAR, 1998). In addition, the notified polymer contains a structural alert for sensitisation (Barratt, 1994).

Based on this information and observations of human exposure to other maleic acid esters (see below) it is anticipated that the notified polymer may cause skin sensitisation.

Repeated Dose Toxicity
No repeat dose studies were provided for the notified polymer. Although summaries for three repeat dose studies were provided for maleic acid, due to insufficient information it was not possible to determine NOAEL for these studies.

In a 28 day oral toxicity study in rats, slight reduced (unspecified) weight gain in high dose animals (3250 ppm) was recorded, one high dose animal died and there was a statistically significant difference (unspecified) compared to the control group in relative adrenal weight in all dose groups (300, 100, 3250 ppm). In a 53 day study no adverse effects were reported for rats dosed with up to 2 mg/day. The very limited study details, however, precludes the establishment of a NOAEL. In a 2 year carcinogenicity study, excess mortality was noted in all dose groups (250, 500, 750 mg/kg bw). In addition, retarded growth and kidney damage was reported for animals dosed at 500 and 750 mg kg/bw with liver and testes injury being noted in high dose animals. Under the conditions of this study, the NOAEL would be < 250mg/kg bw.

In an combined repeat dose and reproductive/development toxicity screening test with dibutylmaleinate , the following adverse effects were reported for animals dosed at 300 mg/kg bw/day: significantly lower body weights, significantly higher albumin, total protein and bilirubin, renal tubular lesions and increased liver and kidney weights. The NOAEL in this study was considered to be 95mg/kg bw/day (SIAR, 1998).

Mutagenicity.
No genotoxicity studies were provided for the notified polymer. Maleic acid was not mutagenic in five Ames tests and not clastogenic to vicia root tip cells treated in vitro. Maleic acid was however found to be clastogenic to human fibroblast cells treated in vitro.

Carcinogenicity.
There was no evidence of carginogenicity in a two year study with maleic acid.

Observations on Human Exposure.
A compound of this class, diethyleneglycol maleate, was reported as causing allergic contact dermatitis in car repair workers (Pfaffli, 2002, Tarvainen, 1993). In addition, a strong sensitising effect and development of contact dermatitis was reported in humans occupationally exposed to glues containing dibutylmaleinate (SIAR, 1998)

Hazard classification for health effects.

Due to the limited toxicological data for the notified polymer, only eye irritation can be classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002). The classification and labelling details are:

R36 Irritating to eyes

Based on the assumption that analogue data are acceptable and indicative of toxicity of the notified polymer, the following additional classification and labelling should apply:

R43 May cause sensitisation by skin contact

9.2.4. Occupational health and safety – risk characterisation

Based on the toxicity data provided for the notified polymer and the proposed analogue maleic acid, the notified polymer is an eye irritant, slight skin irritant and may cause sensitisation by skin contact. In addition, the notified polymer may have an adverse impact on kidney function.

Workers who have the potential for exposure to the notified polymer during routine operations include workers loading and unloading the dye machines and quality control workers with the greatest level of exposure predicted to be for workers involved in unloading of the dye machine. The notified polymer is present at a concentration of < 5% in the dye and on the fabric. At this concentration the risk of irritation to the skin and eyes is expected to be low, however, the risk of sensitisation cannot be ruled out. As such, it is recommended that these workers wear protective eyewear, chemical resistant industrial clothing (coveralls) and impermeable gloves.

Exposure to notified polymer during unloading of dyeing machine was estimated to be 0.14 mg/kg bw/day. No NOAEL could be established from the repeat dose toxicity studies for maleic acid (the proposed analogue) and as such a margin of exposure cannot be established. A Another maleic acid ester, dibutylmaleinate, is reported to be both a skin sensitiser and have adverse effects on the kidney. It is considered that sensitisation effects would be observed at exposure levels significantly lower than the NOAEL established for this chemical (95 mg/kg bw/day). Similarly, the risk of adverse systemic effects for workers involved with the unloading of the dyeing machine is expected to be low due to the low level of exposure predicted and the recommended use of PPE due to the risk of sensitisation.

Due to the automated nature of the dye formulation process the risk to process workers is expected to be negligible. However, due to the nature of the notified polymer, in the event of a spill or machine malfunction, workers should wear protective eyewear, chemical resistant industrial clothing (coveralls) and impermeable gloves.

Following drying of the textile product, the risk to workers handling the fabric treated with the notified polymer is expected to be negligible.

9.2.5. Public health – risk characterisation

Exposure to the notified polymer is predicted to be negligible and as such the risk to public health is expected to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Due to the limited toxicological data for the notified polymer, only eye irritation can be classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2002). The classification and labelling details are:

R36 Irritating to eyes

Based on the assumption that analogue data are acceptable and indicative of toxicity of the notified polymer, the following additional classification and labelling should apply:

R43 May cause sensitisation by skin contact

and

Classification of notified polymer using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations, 2003) was not possible as the notified polymer cannot be isolated and the available toxicity data refers to a formulation. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio, the chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used in the proposed manner

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of Miralan HTP provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for Miralan HTP provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The NOHSC Chemicals Standards Sub-committee should consider the following health hazard classification for the notified polymer:
  - R36 Irritating to eyes

- Based on analogue data, the notifier should give the notified polymer the following additional health hazard classification:
  - R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified polymer:
  - Conc≥ 20%: R36, R43
  - 1%≤ conc< 20%: R43

Health Surveillance

- As the notified polymer is a potential skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

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, the dye solution containing the notified polymer and wet textiles treated with the notified polymer:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure during handling of, the notified polymer as introduced, the dye solution containing the notified polymer and wet textiles treated with the notified polymer:
  - Protective eyewear, chemical resistant industrial clothing and impermeable gloves;

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

- 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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer and chemical waste should be disposed of by incineration.

Emergency procedures

- Spills/release of the notified polymer should be handled by containing the spill and absorbing the spilled material in absorbent material (eg. sand, earth). Scoop into labelled containers and seal for appropriate disposal as chemical waste.

12.1. 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(1) of the Act; if
  - products formulated with the notified polymer are made available to the public.

or

(2) 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.

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