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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME  
(NICNAS)**

**PUBLIC REPORT**

**Polymer in Hardener W-501**

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 conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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

This 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**

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## SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1681	C.I. Ceramics (Aust.) Pty Ltd	Polymer in Hardener W-501	Yes	< 1 tonne per annum	Component of coatings

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the Table below.

<i>Hazard classification</i>	<i>Hazard statement</i>
Skin sensitisation (Category 1)	H317 – May cause an allergic reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrases:

R43            May cause sensitisation by skin contact

### Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers, provided that adequate measures are in place to minimise exposure to the notified polymer and protect against the risk of skin sensitisation.

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

### Environmental risk assessment

On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

### Recommendations

#### REGULATORY CONTROLS

##### Hazard Classification and Labelling

- The notified polymer should be classified as follows:
  - H317 – May cause an allergic reaction
- The following classifications should be considered for use for products/mixtures containing the notified polymer:
  - Conc. ≥1%: H317

##### Health Surveillance

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

## CONTROL MEASURES

### Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Automated and enclosed processes for mixing and coating, where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid contact with skin
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Coveralls, safety glasses, impervious gloves and safety boots

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2012) or relevant State or Territory Code of Practice.
- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

### 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 polymer 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 polymer has a number-average molecular weight of less than 1000 Da;
  - the concentration of the polymer in coatings is proposed to exceed 2%;
  - coatings containing the notified polymer are proposed to be applied other than through a robotic sprayer within a spray booth;

or

- (2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from component of coatings, or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the 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 product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

### **ASSESSMENT DETAILS**

#### **1. APPLICANT AND NOTIFICATION DETAILS**

##### APPLICANT(S)

C I Ceramics (Aust) Pty Ltd (ABN: 51 003 988 056)  
22 Rivulet Crescent  
ALBION PARK RAIL 2527 NSW

##### NOTIFICATION CATEGORY

Limited: Synthetic polymer with  $M_n \geq 1000$  Da.

##### EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and 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, Density, Vapour pressure, Absorption/Desorption, Partition coefficient, Dissociation constant, Particle size, Flash point, Flammability limits, Autoignition temperature, Explosive properties, Oxidising properties and Reactivity

##### PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

No

##### NOTIFICATION IN OTHER COUNTRIES

Canada

#### **2. IDENTITY OF CHEMICAL**

##### MARKETING NAME(S)

Hardener W-501

##### MOLECULAR WEIGHT

> 1,000 Da

## ANALYTICAL DATA

Reference IR and GPC spectra were provided.

**3. COMPOSITION**

## DEGREE OF PURITY

> 98%

## LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

The notified polymer will be imported in an aqueous solution. All of the residual monomer content will be available for release into the solution.

## DEGRADATION PRODUCTS

The notified polymer is stable under normal use conditions and in aqueous solutions at pH 7 and 9. Some reaction occurs under acidic conditions (pH 1.2 – 4.0).

**4. PHYSICAL AND CHEMICAL PROPERTIES**

APPEARANCE AT 20 °C AND 101.3 kPa: light yellowish transparent liquid with slight odour\*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Expected to be < 0 °C
Boiling Point	> 100 °C	MSDS*
Density	1030 kg/m <sup>3</sup> at 20 °C	MSDS*
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight.
Water Extractability	8.5% at pH 1.2 43.7% at pH 7 45.5% at pH 9	Measured
Hydrolysis as a Function of pH	Stable in aqueous solutions at pH 7 and 9. Some hydrolysis occurred under acidic conditions (pH 4.0)	Measured
Partition Coefficient (n-octanol/water)	Not determined	Expected to have a low log Pow due to the ready water solubility of the notified polymer.
Adsorption/Desorption	Not determined	The notified polymer is a non-ionic polymer and has a high molecular weight, hence, a significant portion of the notified polymer is expected to partition to solid/sludge.
Dissociation Constant	Not determined	Does not contain dissociable functionality.
Particle Size	Not determined	Imported in an aqueous solution.
Flash Point	Not determined	Expected to be high based on the low vapour pressure.
Flammability	Not determined	Imported in an aqueous solution. Not expected to be flammable under normal conditions of use.
Autoignition Temperature	Not determined	Imported in an aqueous solution. Not expected to autoignite under normal conditions of use.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties.

\*Product containing the notified polymer at 40% in an aqueous solution

## DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

#### Reactivity

The notified polymer is expected to be stable under normal conditions of use.

#### Physical hazard classification

Based on the limited submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

## 5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as an aqueous solution at 40% concentration in 5 kg jerry cans. It will not be reformulated or repackaged in Australia.

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

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

#### PORT OF ENTRY

Melbourne and Sydney

#### IDENTITY OF RECIPIENTS

C I Ceramics (Aust) Pty Ltd

#### TRANSPORTATION AND PACKAGING

The notified polymer will be imported as an aqueous solution at 40% concentration in 5 kg jerry cans. It will be transported by road from the dock side to the notifier's warehouse.

#### USE

The notified polymer will be used as a hardener in a two-pack, heat-cured coating for rubber articles.

#### OPERATION DESCRIPTION

The notified polymer will be used as a component of a two-part coating system. The notified polymer will be present in Part B of the system. Part A: Part B weight ratio will be 100:5. Thus, the concentration of the notified polymer in the mixed coating will be 2%. The required amount of Part B will be manually poured out of the jerry can into a weighing vessel and then poured into the mixing vessel containing Part A. The two parts will be mixed in a closed vessel using a mechanical mixer. The coating will be pumped from the mixer to a robotic sprayer within a spray booth, where the rubber articles will be coated. The coated rubber will be heat dried prior to leaving the spray booth.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1. Exposure Assessment

#### 6.1.1. Occupational Exposure

#### CATEGORY OF WORKERS

Category of Worker	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport and storage	2-4	24
Plant operators	0.25	200
Maintenance	1-2	12

## EXPOSURE DETAILS

*Transport and storage*

Transport and storage workers may come into contact with the notified polymer at 40% concentration only in the event of accidental rupture of containers.

*Plant operators*

Dermal and ocular exposure to the coating containing the notified polymer at a concentration of up to 40% is possible during accidental spills, opening containers, manual pouring, mixing parts A and B, and connecting and disconnecting hoses and pumping equipment. Exposure during these operations will be minimised by the use of personal protective equipment, such as impervious gloves, coveralls, safety glasses and safety boots. Since the coating will be applied robotically within a spray booth which is fitted with local exhaust ventilation and air filters, inhalation exposure during the spray process is likely to be minimal. As workers will handle the treated rubber substrate only after the coating has been fully dried, the notified polymer will be adsorbed onto the rubber substrate at this stage and will not be available for exposure.

**6.1.2. Public Exposure**

The notified polymer will not be made available to the public. The public may come into contact with rubber surfaces that have been treated with the coating containing the notified polymer. However, the coating will be in a dried form adsorbed onto the rubber surface and thus the notified polymer will not be available for exposure.

**6.2. Human Health Effects Assessment**

The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity
Guinea pig, skin sensitisation – adjuvant test	evidence of sensitisation
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation

*Toxicokinetics, metabolism and distribution*

Based on the high molecular weight (> 1000 Da) of the notified polymer, the potential of the notified polymer to cross the gastrointestinal (GI) tract or to be dermally absorbed after exposure is expected to be limited. Furthermore, it contains a relatively low percentage of low molecular weight species (< 5% < 1000 Da).

*Acute toxicity*

The notified polymer was of low acute oral toxicity (LD50 >2000 mg/kg bw) in rats.

*Sensitisation*

The notified polymer contains a structural alert for skin sensitisation. The notified polymer was negative in a mouse Local Lymph Node Assay (LLNA) carried out according to a method similar to OECD test guideline 442B (non-radioactive). However, a Guinea Pig Maximisation Test (GPMT) on the notified polymer carried out according to OECD test guideline 406 gave a positive result, indicative of skin sensitisation potential for the polymer.

Dose selection for the LLNA test was not adequately justified, with doses chosen to be the same as those of the positive controls. The test guideline recommends that a prescreen test should be performed to determine the highest dose level that maximises exposure whilst avoiding systemic toxicity and/or excessive local irritation. However, a prescreen test was not conducted. Accordingly, the selection of test doses was not able to ensure maximised exposures to the test substance. Despite the positive controls behaving appropriately, proliferation reactions with the test substance were minimal. The lack of assurance of maximised exposures to the test substance raises the possibility that the results seen in the LLNA may be a false negative.

It is noted that the substance examined in the GPMT was not well characterised, with levels and identity of impurities, as well as the molecular weight distribution, unknown. However, the test appeared to be adequately conducted. Dose selection for intradermal and topical induction were conducted on the basis of pretests to determine the highest dose associated with mild to moderate irritation in the absence of systemic toxicity. Dose selection for topical challenge was conducted on the basis of a pretest to determine the highest non-irritant concentration.



In the main test, challenge at 75% produced more severe reactions than those seen during induction at 100%. Desquamation was observed following challenge but not during induction. In addition, control animals (presumably challenged in a similar fashion to test animals) showed no reactions.

Overall, there appeared no significant issues with the conduct of the GPMT to suggest that the result was a false positive. In addition, positive skin sensitisation reactions were observed in a large proportion of the animals (70%), far exceeding the 30% response rate required for classification according to this test method.

Whilst the relatively high molecular weight of the notified polymer is expected to limit the extent of dermal absorption and perhaps also the potential for skin sensitisation, it cannot be completely ruled out. It may be argued that a LLNA test provides a more realistic indication of the sensitisation potential, given that it is applied dermally and is not injected into the skin, as compared to the GPMT where injection into the skin takes place. However, the criteria for classification as a skin sensitizer require positive results from an appropriate animal study, which includes response in at least 30% of animals in an adjuvant type test method.

Based on the weight of the available evidence, it is concluded that the notified polymer should be considered to meet the criteria for classification as a skin sensitizer.

#### **Health hazard classification**

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following Table.

<i><b>Hazard classification</b></i>	<i><b>Hazard statement</b></i>
Skin sensitisation (Category 1)	H317 – May cause an allergic reaction

Based on the available information, the notified polymer is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrases:

R43            May cause sensitisation by skin contact

### **6.3. Human Health Risk Characterisation**

#### **6.3.1. Occupational Health and Safety**

The notified polymer is classified as a skin sensitizer.

Workers may be exposed to the notified polymer at up to 40% concentration during mixing and at up to 2% during application of coatings. Strict adherence to the PPE and engineering controls recommendations is expected to mitigate the risk of sensitisation effects, due to negligible worker contact with the notified polymer. After the coating has been applied and cured, the notified polymer will be bound into an inert matrix and will not be bioavailable for further exposure.

Overall, the risk to workers from use of the notified polymer is not considered unreasonable, provided that adequate measures are in place to minimise exposure to the notified polymer and protect against the risk of skin sensitisation.

#### **6.3.2. Public Health**

No public exposure to the notified polymer is expected from the cured coated rubber. As such, the risk to the public from the use of the notified polymer is not considered to be unreasonable.

## **7. ENVIRONMENTAL IMPLICATIONS**

### **7.1. Environmental Exposure & Fate Assessment**

#### **7.1.1. Environmental Exposure**

##### **RELEASE OF CHEMICAL AT SITE**

The notified polymer will be imported to Australia as an aqueous solution at 40% concentration for industrial use as a hardener in a two-pack, heat-cured coating for rubber articles. The release of the notified polymer to the environment is not expected from manufacturing and reformulation as these activities will not occur in Australia.

##### **RELEASE OF CHEMICAL FROM USE**

Release of the notified polymer to the aquatic environment is not expected to be significant during use as residues in equipment washings and storage containers are expected to be collected and disposed of to landfill. The notified polymer is expected to be used only in industrial applications. Coating containing the notified polymer is expected to be applied by robotic spray application equipment to rubber substrates. The release from coating overspray during use is anticipated to be collected via a forced air fume collection system attached to the spray booths. The collected uncured coating is expected to be recycled into the next batch or disposed of to landfill after drying by heating. The notified polymer (up to 2% of the total import volume) is expected to be disposed of to landfill as wastes from end use.

##### **RELEASE OF CHEMICAL FROM DISPOSAL**

Coated rubber articles containing the notified polymer are expected to be disposed of to landfill at the end of their useful lives. The notified polymer is expected to be in a cured state and is expected to tightly bind to the rubber substrate.

#### **7.1.2. Environmental Fate**

No environmental fate data were submitted. The majority of introduced notified polymer is expected to be cured into a coating matrix and adsorbed onto the rubber substrate. The notified polymer will share the fate of the coated rubber substrate. The notified polymer is expected to be tightly bound to the rubber and, in this form, is not expected to be bioavailable or biodegradable. The notified polymer in solid waste disposed of to landfill is not expected to be mobile due to its high molecular weight and will slowly degrade to form water and oxides of carbon and nitrogen. The notified polymer is not expected to be released to the aquatic environment according to the assessed use pattern. The potential for bioaccumulation of the notified polymer is low due to its high molecular weight, relatively high water solubility and its limited release to surface waters.

#### **7.1.3. Predicted Environmental Concentration (PEC)**

The predicted environmental concentration (PEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

### **7.2. Environmental Effects Assessment**

No ecotoxicity data were submitted. Since the notified polymer is a non-ionic polymer, it is not likely to be hazardous to the environment, and is generally of low concern to the aquatic environment. Furthermore, the majority of the notified polymer applied to rubber substrates will be cured to form a coating matrix and is not expected to be bioavailable.

#### **7.2.1. Predicted No-Effect Concentration**

A Predicted No-Effect Concentration (PNEC) was not calculated as no ecotoxicological data were submitted and there will be very low potential for aquatic exposure.

### **7.3. Environmental Risk Assessment**

A Risk Quotient ( $RQ = PEC/PNEC$ ) is unable to be quantified as a PEC and PNEC were not calculated. There is no significant aquatic release of the notified polymer anticipated based on the reported use pattern. Moreover, after curing, the majority of the imported quantity of notified polymer will be incorporated into a coating matrix and is not expected to be mobile, bioavailable, nor readily biodegradable. On the basis of the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

<b>Water Extractability</b>	Reported as solubilisation rate of component carbon (%): 8.5% at pH 1.2 43.7% at pH 7 45.5% at pH 9
Method	Handling of the Knowledge Obtained of the Composition and Properties (March 25, 2004, Notification No. 0325002, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare; March 19 2004, No. 4, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry: No. 040325002, Environmental Policy Bureau, Ministry of the Environment, Finally amended September 16, 2004).
Remarks	Test concentrations of 2000 mg/L were prepared in buffer solutions of pH 1.2, 4, 7 and 9. After the test solutions were stirred at $40 \pm 2$ °C (24 hours for the test solution of pH 1.2 and two weeks for the rest), the solutions were equilibrated at $25 \pm 2$ °C and were filtered under a reduced pressure. The filtrates were analysed for total organic carbon (TOC). TOC analysis was not performed for the test solution of pH 4 as it contained potassium hydrogen phthalate.
Test Facility	Kurume (2005)

<b>Hydrolysis as a Function of pH</b>	Stable at pH 7 to 9 Some hydrolysis occurred under acidic conditions (pH 4.0)
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Method	Handling of the Knowledge Obtained of the Composition and Properties (March 25, 2004, Notification No. 0325002, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare; March 19 2004, No. 4, Manufacturing Industries Bureau, Ministry of Economy, Trade and Industry: No. 040325002, Environmental Policy Bureau, Ministry of the Environment, Finally amended September 16, 2004).
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<i>pH</i>	<i>T (°C)</i>	<i>t<sub>1/2</sub> &lt;hours or days&gt;</i>
4	$25 \pm 2$ °C	Some hydrolysis occurred under acidic conditions
7	$25 \pm 2$ °C	Stable
9	$25 \pm 2$ °C	Stable

Remarks	Test concentrations of 2000 mg/L were prepared in buffer solutions of pH 1.2, 4, 7 and 9. After the test solutions were stirred at $40 \pm 2$ °C (24 hours for the test solution of pH 1.2 and two weeks for the rest), the solutions were equilibrated at $25 \pm 2$ °C and were filtered under a reduced pressure. The filtrates were then ultrafiltered using centrifugal filter units to conduct IR analyses. Then the residues on the centrifugal filters were dried and also measured in the same manner described above. The IR spectrum for the filtrate of pH 1.2 could not be measured because the concentration of the test item in the filtrate was under the detection limit. Absorption peaks at its corresponding wavelength were observed in the IR spectra before the stability test for pH 1.2 and pH 4. After the stability test, however, those peaks for the filter cakes (residues) disappeared. It was assumed that the inorganic acid or carboxylic acid in the test solution reacted with a functional group present in the test item. No difference was observed in the IR spectra for the filter cakes (residues) and for the filtrates of the test solutions before and after the stability test for pH 7 and pH 9. It is considered that the test item is essentially stable under the conditions of pH 7 to pH 9.
Test Facility	Kurume (2005)

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

### B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer	
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.	
Species/Strain	Rat/Crj:CD(SD)	
Vehicle	Water	
Remarks - Method	No protocol deviations	
RESULTS		
<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
5 per sex	2000	0
LD50	> 2000 mg/kg bw	
Signs of Toxicity	No treatment-related abnormal clinical signs were observed.	
Effects in Organs	No treatment-related abnormalities were observed during macroscopic examination.	
Remarks - Results	For one female animal slight decrease in body weight was observed on day 3 after dosing, but on the following days its body weight increased constantly.	
CONCLUSION	The notified polymer is of low toxicity via the oral route.	
TEST FACILITY	Hita Research Laboratories (1995)	

### B.2. Skin sensitisation

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 406 Skin Sensitisation - <Magusson and Kligman Maximisation Method>.
Species/Strain	Guinea pig/male albino Dunkin Hartley
PRELIMINARY STUDY	Maximum Non-irritating Concentration: intradermal: Irritation was observed at all concentrations used for the preliminary test topical: 100% (though noting that transient irritation was observed at 1 hour and this had resolved by the 24 hour observation)
MAIN STUDY	
Number of Animals	Test Group: 20                      Control Group: 10
INDUCTION PHASE	Induction Concentration: intradermal: 0.1% v/v topical: 100%
Signs of Irritation	<i>Intradermal induction sites</i> Moderate and confluent erythema was noted in test group animals. Discrete or patchy to moderate and confluent erythema was noted in control group animals.  <i>Topical induction sites</i> Moderate and confluent erythema and very slight oedema were noted in test group animals. No signs of erythema or oedema were noted in control group animals. Bleeding from the injection sites was noted in all test group animals and four control group animals.
CHALLENGE PHASE	topical: 75 and 100%

Remarks - Method No significant protocol deviations

## RESULTS

Animal	Challenge Concentration	Number of Animals Showing Skin Reactions after: challenge	
		24 h	48 h
Test Group	100%	20/20	14/20
	75%	20/20	14/20
Control Group	100%	0/10	0/10
	75%	0/10	0/10

Remarks - Results No skin reactions were noted in any control group animals.

*Topical challenge of 100% test substance*

Skin responses considered to indicate a positive response to challenge were observed in fourteen animals (discrete or patchy to moderate confluent erythema).

Transient challenge reactions (discrete or patchy erythema) were noted at the topical challenge sites of six test group animals at the 24-hour observation. These reactions were not apparent at the 48-hour observation and were therefore not attributed to sensitisation.

Discrete or patchy erythema was observed in thirteen test group animals at the 48 hour observation. Severe desquamation, which prevented evaluation of erythema, was noted at the topical challenge site of one test group animal at the 48-hour observation and the reactions in this animal were attributed to sensitisation. Desquamation was noted at the topical challenge sites of five test group animals at the 48-hour observation.

*Topical challenge of 75% test substance*

Discrete or patchy to moderate and confluent erythema, with or without very slight oedema was noted in all animals at 24 hours and in fourteen animals at 48 hours. Severe desquamation, which prevented evaluation of erythema, was noted at the topical challenge sites of six test group animals at the 48-hour observation and the reactions in these animals were attributed to sensitisation. Desquamation was noted at the topical challenge sites of nine test group animals at the 48-hour observation.

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

TEST FACILITY SafePharm Laboratories (2002)

### B.3. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified polymer

METHOD Similar to OECD TG 442B Skin Sensitisation: Local Lymph Node Assay BrdU-ELISA

Species/Strain Mouse/SPF:CBA/JN CrLj

Vehicle Acetone/olive oil (4:1 v/v)

Remarks - Method Dose selection of the test substance was not adequately justified by the study authors and was not determined on the basis of a pre-screen test.

## RESULTS

Concentration (% w/w)	Mean lymph node weight (mg)	Stimulation Index (Test/Control Ratio)
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<i>Test Substance</i>		
0 (vehicle control)	3.4 ± 0.23	1.00 ± 0.10
1	4.2 ± 0.42	1.16 ± 0.09
10	4.0 ± 0.56	1.16 ± 0.12
50	4.4 ± 0.22	1.29 ± 0.11
<i>Positive Control</i>		
2,4-dinitrochlorobenzene (1%)	21.2 ± 0.38	9.36 ± 0.51
isoeugenol (10%)	8.3 ± 1.50	3.20 ± 0.54
α-hexylcinnamic aldehyde (50%)	9.9 ± 0.37	4.17 ± 0.28

Remarks - Results	<p>The notified polymer elicited no lymphocyte proliferative response at any concentration tested, and the stimulation indices of the notified polymer at each test concentration were significantly lower than that of concurrent positive control groups.</p> <p>No animals showed any abnormalities with regard to general condition or body weight change.</p>
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified polymer under the test conditions employed.
TEST FACILITY	Hita Laboratory (2006)

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