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

**FULL PUBLIC REPORT**

**Tego Rad 2650 and Tego RC 902**

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 the Environment and Water Resources.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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**

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## **FULL PUBLIC REPORT**

|                                      |
|--------------------------------------|
| <b>Tego Rad 2650 and Tego RC 902</b> |
|--------------------------------------|

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

#### APPLICANT(S)

International Sales and Marketing Pty Ltd (ABN 36 467 259 314) of 262 Highett Road, Highett, VIC 3190

#### NOTIFICATION CATEGORY

Limited: Synthetic polymer with NAMW  $\geq 1000$  Da

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

Data items and details claimed exempt from publication:

Chemical Name, CAS number, Structural Formula Molecular Weight, % Low molecular weight species, Purity, Impurities, Analytical data, Identity of Manufacturer/Recipients, Import volume and Use Details.

#### VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

No variation to the schedule of data requirements is claimed.

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

CEC/721

#### NOTIFICATION IN OTHER COUNTRIES

China (2005) and Canada (2000)

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

#### MARKETING NAME(S)

Tego Rad 2650

Tego RC 902

#### MOLECULAR WEIGHT

Number Average Molecular Weight (Mn) >1,000 Da

#### ANALYTICAL DATA

Reference NMR, IR, GPC, and UV spectra were provided.

### **3. COMPOSITION**

#### DEGREE OF PURITY

>95%

#### ADDITIVES/ADJUVANTS

None

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

None

### **4. PHYSICAL AND CHEMICAL PROPERTIES**

#### APPEARANCE AT 20°C AND 101.3 kPa

Yellowish, viscous liquid that is clear to slightly turbid.

| Property   | Value                               | Data Source/Justification   |
|--|-------------------------------------|---|
| Freezing Point                                   | <-90°C                              | Measured  |
| Boiling Point                                    | >200°C at 101.3 kPa                 | Measured  |
| Density  | 985 kg/m <sup>3</sup> at 20°C       | Measured  |
| Viscosity, dynamic                               | ~550 mPa.s at 25°C                  | Measured (MSDS)   |
| Vapour Pressure                                  | <1.47×10 <sup>-11</sup> kPa at 20°C | Measured  |
| Water Solubility                                 | <1×10 <sup>-3</sup> g/L at 20°C     | Measured  |
| Hydrolysis as a Function of pH                   | Not determined                      | The notified polymer is not soluble in water                                  |
| Partition Coefficient ( <i>n</i> -octanol/water) | Not determined                      | The notified polymer is not soluble in water                                  |
| Adsorption/Desorption                            | Not determined                      | The HPLC method and QSAR calculations are not appropriate for this polymer.   |
| Dissociation Constant                            | Not determined                      | No predicted modes of dissociation  |
| Particle Size                                    | Not applicable                      | The notified polymer is a liquid  |
| Flash Point                                      | 152°C at 102.96 kPa                 | Measured (test report)  |
|  | 128°C                               | Measured (MSDS)   |
| Flammability                                     | Not determined                      | Not expected to be highly flammable, based on its physicochemical properties. |
| Autoignition Temperature                         | 455°C                               | Measured  |
| Explosive Properties                             | Not explosive                       | Estimated based on the structural formula                                     |
| Oxidising Properties                             | Not oxidising                       | Estimated based on the structural formula                                     |

#### DISCUSSION OF PROPERTIES

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

Based on the flash point of the notified polymer (128-152°C), it is not a Class 3 Flammable liquid.

#### Reactivity

The notified polymer is not reactive with water or air under normal conditions (<150°C), and is predicted to not possess oxidising properties.

## 5. INTRODUCTION AND USE INFORMATION

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

The notified polymer (100% concentration) will be imported in 200 kg steel drums. It will not be manufactured in Australia.

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

| Year   | 1   | 2   | 3   | 4   | 5   |
|--------|-----|-----|-----|-----|-----|
| Tonnes | <50 | <50 | <50 | <50 | <50 |

#### PORT OF ENTRY

Port of Melbourne or Port of Adelaide in mixed FCL with other products.

#### TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 200 kg steel drums (supplied as four drums per pallet). These will be transported by truck from port to store and from store to customer. Pallets are stored in a designated chemicals storage area on site.

#### USE

The notified polymer will be used as a component of coatings for self-adhesive paper. The end-use for the certificate period will be in labels for consumer products.

#### OPERATION DESCRIPTION

Drum-lifting equipment will be used to decant the notified polymer from 200 kg drums into a mixing tank (in a 70:30 ratio with other additives). This mixture (70% notified polymer) will be pumped through a closed system into the flexo-chamber of the coating equipment. This flexo-chamber will coat the plastic liner as it passes

through rollers. An adhesive and a face paper will also be combined in the system to form a self-adhesive paper stock. The notified polymer on the liner will undergo UV curing in an oxygen free chamber to form a thin, solid layer. The application equipment will be cleaned using a liquid solvent wash, with the waste contained in 200 L drums.

The self-adhesive paper stock will be sold to industrial customers for use in production line labelling of consumer products.

## 6. HUMAN HEALTH IMPLICATIONS

### 6.1 Exposure assessment

#### 6.1.1 Occupational exposure

##### NUMBER AND CATEGORY OF WORKERS

| <i>Category of Worker</i> | <i>Number</i> | <i>Exposure Duration<br/>(hours/day)</i> | <i>Exposure Frequency<br/>(days/year)</i> |
|---------------------------|---------------|--|---|
| Storeman (receiving)      | 1             | 0.5                                      | 1   |
| Operator                  | 1             | 0.5                                      | 10  |

##### EXPOSURE DETAILS

Dermal or ocular exposure is possible during the transfer of the notified polymer into the mixing tank, resulting from spillages from drums. Exposure of workers may also occur during the connection and disconnection of pumping lines at each end of a sustained production run or during maintenance. Incidental skin or eye contact will be minimised by the wearing of gloves and safety glasses by workers, especially where the notified polymer will be present in an open vessel.

Significant inhalation exposure to the notified polymer is not expected, as the method of application used is not expected to produce significant aerosols. In addition, the notified polymer has a low vapour pressure. Heating will not be used during production, so workers are unlikely to be exposed to vapours containing the notified polymer. Oral absorption is not expected during normal handling.

During storage and industrial use of the notified polymer, there will be potential for spillage where clean up and disposal would be required. Suitable protective clothing will be worn, including gloves and goggles, during these processes.

Following UV curing of the notified polymer on the label, primarily dermal exposure to the notified polymer may occur following contact with finished self-adhesive papers. This exposure is expected to be negligible, as the notified polymer will be bound within a cured polymeric matrix.

#### 6.1.2. Public exposure

The product containing the notified polymer will be used in industrial applications, and the public will not be exposed to the notified polymer in its liquid form. In finished products, minimal public exposure to the notified polymer is expected. Dermal, or potentially oral exposure to the adhesive material on “peeled off” labels may be possible, but within this adhesive surface the notified polymer will be cured into a matrix, minimising any potential for exposure.

### 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 B.

| <i>Endpoint</i>                                    | <i>Result and/or Assessment Conclusion</i> |
|--|--|
| Rat, Acute oral toxicity*                          | LD <sub>50</sub> >2000 mg/kg bw            |
| Rabbit, eye irritation*                            | Irritating                                 |
| Guinea pig, skin sensitisation – Maximisation test | No evidence of sensitisation               |
| Genotoxicity – bacterial reverse mutation          | Non-mutagenic                              |

\* Test reports unavailable (see below under *Toxicity and Irritation and Sensitisation*).

#### ***Toxicokinetics, metabolism and distribution***

No experimental evidence is available to suggest that the notified chemical is able to be absorbed following exposure. The notified polymer is of high molecular weight (NAMW >1000 Da), and is primarily lipophilic in nature (based on its lack of water solubility and structural formula). Therefore, significant transdermal absorption would not be expected; some uptake is expected, but penetration into the epidermis is expected to be slow and/or hampered by favourable interactions in the stratum corneum. Absorption following oral exposure may occur through solubilisation by bile salts, but this will be hampered by the high molecular weight of the notified polymer. Overall, the notified polymer is not expected to be absorbed to a significant degree, and so has the potential to induce mainly local effects at the site of exposure.

### ***Toxicity***

The notified polymer was reported to be of low acute oral toxicity in a rat study, and has an LD<sub>50</sub> of >2000 mg/kg bw (mentioned in BioChem, 1991). This result resembles that which might be expected based on analogy with similar polymers. No information is available that establishes the chronic toxicity of the notified polymer.

### ***Irritation and Sensitisation***

The notified polymer is expected to cause eye irritation of unknown severity, on the basis of test data cited by the notifier for a similar polymer (NAMW ~1000 Da). This data has not been reviewed. No information was available regarding the ability of the notified polymer to cause skin irritation, but based on its structural formula, slight dermal irritation might be expected.

The notified polymer was also considered to be a possible sensitiser on the basis of its structural formula. However, test data from a Guinea pig maximisation study carried out using the notified polymer were negative, indicating that it is unlikely to induce dermal sensitisation in humans upon repeated or prolonged exposure.

### ***Mutagenicity***

The notified polymer tested negative for mutagenicity in an Ames bacterial reverse mutation study; however, this is not considered sufficient evidence to conclusively state that it would be non-mutagenic to humans. Given its other characteristics, however, it might not be expected to be mutagenic or genotoxic *in vivo*.

Based on advice from the notifier, the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

R36 Irritating to Eyes.

## **6.3. Human health risk characterisation**

### **6.3.1. Occupational health and safety**

The notified polymer is expected to display generally low toxicity, limited to local irritant effects. The anticipated exposure to the notified polymer is expected to be limited, as little direct handling occurs, and because it will be used in semi- or fully automated applications (manufacture of self-adhesive paper). Adverse ocular and dermal effects on workers resulting from accidental or incidental exposure are likely to be controlled through the use of the proposed PPE and through the application of good industrial hygiene practices. Therefore, the risk to workers from use of the liquid notified polymer is expected to be acceptable. The risk presented by contact of workers with the notified polymer on finished self-adhesive papers is considered to be negligible, as the notified polymer will be bound with in a cured polymeric matrix.

### **6.3.2. Public health**

Members of the public will only be exposed to end-use products (such as self-adhesive labels) in which the notified polymer will be bound with in a cured polymeric matrix. Therefore, the risk presented is considered to be acceptable, due to its expected low exposure and its expected low toxicity.

## **7. ENVIRONMENTAL IMPLICATIONS**

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

#### **7.1.1 Environmental Exposure**

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

The notified polymer is delivered to the site in 200 kg drums after which it is stored in a designated chemicals specific location. Potential sources of environmental release include spillages during storage, and from mixing of the notified polymer with other ingredients in the flexo tank. Accidental spillages will be contained, and collected using absorbent material and disposed of by licensed waste contractors. The manufacture of the end-use product, by coating liner material with the notified polymer as it passes through rollers with addition of an

adhesive and face paper in a closed system, is efficient and likely to generate minimal waste or spillage.

Application equipment will be cleaned with the liquid solvent 'UV wash', and the waste thus generated (containing 0.25% notified polymer) will be placed in 200 L drums stated to be disposed of by incineration – although landfill is more likely.

It is estimated that 0.5% of the notified polymer will be wasted due to off-cuts, out-of-specification batches, and damaged coated paper.

#### RELEASE OF CHEMICAL FROM USE

Minimal release is expected during use, given that the notified polymer is incorporated (cross-linked) into the liner component of the self-adhesive paper. The notified polymer will be retained on the liner after peeling off the label, and is expected to be disposed of to landfill.

#### RELEASE OF CHEMICAL FROM DISPOSAL

Given the low viscosity of the product containing the notified polymer, less than 1 kg of residue is expected to remain in each drum. Recycling is the recommended option for the uncleaned product drums, although the fate of residue at the recycling facility is unclear.

Unused paper and peeled liner waste that is crushed and disposed of to landfill will retain the notified polymer in the paper/adhesive matrix, and is unlikely to be released through leaching.

### 7.1.2 Environmental fate

No environmental fate data were submitted. Minimal wastage is expected given the efficiency of the manufacturing process. Procedures are in place to prevent release to the aquatic environment of unfixed polymer waste resultant from spillage and residue. The notified polymer is cross-linked to the liner during manufacture and any waste products and used liners will be disposed to landfill where slow degradation of the notified polymer will occur.

### 7.1.3 Predicted Environmental Concentration (PEC)

The notified polymer is not expected to be released into the aquatic environment from the manufacture of self-adhesive paper stock, or from the use of this product and no PEC estimation is possible. Spillages, waste from cleaning, and waste paper stock will be disposed of by authorised waste disposal companies. Drum residues will be retained in drums sent for recycling, however, it may be assumed that the notified polymer will not be released to the sewer, as per the license agreement for all recycling facilities.

## 7.2. Environmental effects assessment

No ecotoxicity data were submitted. Polymers without significant ionic charge are not expected to be hazardous in the aquatic environment. The notified polymer is not expected to cross biological membranes, due to its low water solubility and high molecular weight and as such should not bioaccumulate.

### 7.2.1 Predicted No-Effect Concentration (PNEC)

As ecotoxicological data were not submitted, it is not possible to calculate a PNEC.

## 7.3. Environmental risk assessment

The notified polymer is not expected to enter the aquatic environment during manufacture, use or disposal. The notified polymer is cross-linked to liner material as part of an efficient manufacturing process in which little waste is generated, and procedures are in place to prevent releases of unfixed polymer. In addition, the notified polymer with no significant ionic functionality, low water solubility and high molecular weight, is not expected to bioaccumulate or be mobile within a landfill situation.

## 8. CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the available data the notified polymer is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R36 Irritating to eyes

S36/39 Wear suitable protective clothing and eye/face protection.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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.

|                      | <i>Hazard category</i> | <i>Hazard statement</i>                     |
|----------------------|------------------------|---|
| Health Hazard        | 2                      | Irritating to eyes                          |
| Environmental Hazard | -                      | Classification not possible for environment |

#### **Human health risk assessment**

Under the conditions of the occupational settings described, the risk to workers is considered to be acceptable.

When used in the proposed manner the risk to the public is considered to be acceptable.

#### **Environmental risk assessment**

The notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

#### **Recommendations**

##### REGULATORY CONTROLS

##### Hazard Classification and Labelling

- Use the following risk and safety phrases for products/mixtures containing the notified polymer:
  - *R36 Irritating to Eyes. No other known health effects.*
  - *S36/39 Wear suitable protective clothing and eye/face protection.*
  - *S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.*

##### 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:
  - *Avoid direct contact with material*
  - *Avoid spills, and minimise direct handling*
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer, as introduced:
  - *Coveralls, safety goggles/face shield, and 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.

##### Environment



- The following control measures should be implemented by the notifier and end-users to minimise environmental exposure during (manufacture, formulation, use) of the notified polymer:
  - *The product containing the notified polymer should not be allowed to enter drains or waterways, or to be discharged to soil.*
  - *Spillages of product containing the notified polymer should be contained, collected using absorbent material, and disposed of to a licensed waste disposal facility.*

#### Disposal

- The notified polymer should be disposed of by landfill.

#### Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment and collection using absorbent material and disposal to a licensed waste contractor.

### 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 polymer, 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;

or

- (2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of cured adhesive labels on consumer products, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 50 tonnes, or is likely to increase, significantly;
  - if the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical 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.

No additional secondary notification conditions are stipulated.

#### *Material Safety Data Sheet*

The MSDS of 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.

## **APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**

### **Freezing Point** <-90°C

|               |  |
|---------------|--|
| Method        | OECD TG 102 Melting Point/Melting Range.<br>EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.                                       |
| Remarks       | The notified polymer did not solidify upon cooling to -90°C. No melting behaviour was observed by differential scanning calorimetry (DSC). |
| Test Facility | NOTOX (2007)   |

### **Boiling Point** >200°C at 101.3 kPa

|               |  |
|---------------|--|
| Method        | OECD TG 103 Boiling Point.<br>EC Directive 92/69/EEC A.2 Boiling Temperature.  |
| Remarks       | No boiling was observed using DSC. A strong exothermic effect was observed at >200°C, indicating that reaction and/or decomposition of the test substance may have occurred. |
| Test Facility | NOTOX (2007)   |

### **Density** 985 kg/m<sup>3</sup> at 20°C

|               |  |
|---------------|--|
| Method        | OECD TG 109 Density of Liquids and Solids.<br>EC Directive 92/69/EEC A.3 Relative Density. |
| Remarks       | Pycnometer method.   |
| Test Facility | NOTOX (2007)   |

### **Viscosity, dynamic** ~550 mPa.s at 25°C

|             |  |
|-------------|--|
| Method      | German Standard Testing Method DIN 53015 (Höppler falling-ball viscometer) |
| Data Source | Tego RC 902 MSDS   |

### **Vapour Pressure** <1.47×10<sup>-11</sup> kPa at 20°C

|               |   |
|---------------|---|
| Method        | OECD TG 104 Vapour Pressure.<br>EC Directive 92/69/EEC A.4 Vapour Pressure.   |
| Remarks       | The vapour pressure was determined using the isothermal thermogravimetric effusion method. An estimate was obtained through comparison of the evaporation rate for the notified polymer with a regression curve of the logarithms of evaporation rate and vapour pressure, for reference substances of known vapour pressure. The evaporation rate of the notified polymer was lower than that of the reference substance with the lowest evaporation rate (vapour pressure of 1.47×10 <sup>-8</sup> Pa). |
| Test Facility | NOTOX (2007)  |

### **Water Solubility** <1×10<sup>-3</sup> g/L at 20°C

|               |  |
|---------------|--|
| Method        | OECD TG 105 Water Solubility.<br>EC Directive 92/69/EEC A.6 Water Solubility.  |
| Remarks       | The water solubility was determined by the flask method. The result was based the visual identification of undissolved notified polymer in the test sample after stirring. No analytical method was available to detect the notified polymer at aqueous concentrations below 1×10 <sup>-3</sup> g/L. |
| Test Facility | NOTOX (2007)   |

### **Hydrolysis as a function of pH** Not determined

|               |   |
|---------------|---|
| Remarks       | The hydrolysis potential for the notified polymer was not tested due to low water solubility (<1 mg/L) not supporting the available analytical methods. The ester groups are hydrolysable, however, this is not expected to be significant under environmental conditions (pH4-9) given the low water solubility of the notified polymer. |
| Test Facility | NOTOX (2007)  |

**Partition coefficient (*n*-octanol/water)** Not determined

Remarks Given the low water solubility of the polymer (<1 mg/L), the flask shaking, HPLC, and estimation methods cannot be used to determine an accurate value for the partition coefficient. In addition, it is not possible to calculate the partition coefficient from the structural formula. Due to the notified polymer's low water solubility, partitioning to the organic phase might be expected.

Test Facility NOTOX (2007)

**Adsorption/desorption** Not determined

Remarks The adsorption coefficient of the notified polymer cannot be determined using the HPLC method due to the high molecular weight of the polymer. The value may not be estimated due to the inability to determine a value for the partition coefficient. However, given the low water solubility, the notified polymer is expected to associate with soils and sediment.

Test Facility NOTOX (2007)

**Flash Point** 152°C at 102.96 kPa (test report)  
128°C (test conditions unknown – source: MSDS)

Method EC Directive 92/69/EEC A.9 Flash Point.  
ISO 2719 Determination of Flash Point – Pensky Martens Closed Cup Method.  
ASTM D 93 Standard Methods for Flash Point by Pensky Martens Closed Cup Tester  
German Standard Testing Method DIN EN 22719 (DIN 51758) (MSDS)

Test Facility NOTOX (2007); Tego RC 902 MSDS

**Autoignition Temperature** 455°C

Method EC Directive 92/69/EEC A.15 Auto-Ignition Temperature (Liquids and Gases).  
German Standard Testing Method DIN 51794

Test Facility NOTOX (2007)

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

### B.1. Skin sensitisation

|                         |   |
|-------------------------|---|
| TEST SUBSTANCE          | Notified polymer  |
| METHOD                  | OECD TG 406 Skin Sensitisation – Maximisation test.   |
| Species/Strain          | Guinea pig/albino   |
| PRELIMINARY STUDY       | Maximum Non-irritating Concentration (topical) 100%   |
| MAIN STUDY              |   |
| Number of Animals       | Test Group: 20                      Control Group: 20   |
| INDUCTION PHASE         | Induction Concentration:<br>Intradermal: 10% (day 0)<br>topical: 100% (day 7)                           |
| Signs of Irritation     | The study report did not describe irritation events other than those induced by the challenge exposure. |
| CHALLENGE PHASE         |   |
| Challenge concentration | topical: 100% (day 21)  |
| Remarks - Method        | Occlusive dressings were used following dermal exposures in the induction and challenge phases.         |

#### RESULTS

| <i>Animal</i>        | <i>Challenge Concentration</i> | <i>Number of Animals Showing Skin Reactions after 1<sup>st</sup> challenge:</i> |             |
|----------------------|--------------------------------|---|-------------|
|                      |                                | <i>24 h</i>   | <i>48 h</i> |
| <i>Test Group</i>    | 100%                           | 1   | 1           |
| <i>Control Group</i> | 0%                             | 0   | 0           |

Remarks - Results                      No deaths or other toxic signs were observed in the test substance group. One animal showed weak erythema at the test site that persisted for 48 hours. One death occurred in the control group on the day 9 of the test.

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

TEST FACILITY                      BioChem (1991)

### B.2. Genotoxicity – bacteria

|                                  |  |
|----------------------------------|--|
| TEST SUBSTANCE                   | Notified polymer   |
| METHOD                           | OECD TG 471 Bacterial Reverse Mutation Test.<br>EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria.<br>EPA OPPTS 870.5100 Bacterial Reverse Mutation Assay<br>Plate incorporation procedure                                     |
| Species/Strain                   | <i>S. typhimurium</i> : TA1535, TA1537, TA98, TA100, TA102   |
| Metabolic Activation System      | Phenobarbital/β-naphthoflavone-induced rat liver S9 mix  |
| Concentration Range in Main Test | a) With metabolic activation: 0.032 to 5.0 µl/plate (0.03-4.93 µg/plate)<br>b) Without metabolic activation: 0.5 to 5.0 µl/plate (0.49-4.93 µg/plate)  |
| Vehicle                          | Ethanol (96%)  |
| Remarks - Method                 | The preliminary test was performed using strains TA98 and TA100 only.<br><br>The plate-incorporation method was chosen because the solvent chosen (96% ethanol) was incompatible with bacterial survival. The positive controls were dissolved in DMSO or water. |

## RESULTS

| <i>Metabolic Activation</i> |        | <i>Test Substance Concentration (<math>\mu</math>L/plate) Resulting in:</i> |                                  |                      |                         |
|-----------------------------|--------|---|----------------------------------|----------------------|-------------------------|
|                             |        | <i>Cytotoxicity in Preliminary Test</i>                                     | <i>Cytotoxicity in Main Test</i> | <i>Precipitation</i> | <i>Genotoxic Effect</i> |
| <i>Absent</i>               | Test 1 | >5.0  | >5.0                             | >5.0                 | None                    |
|                             | Test 2 |   | $\geq$ 5.0                       | >5.0                 | None                    |
| <i>Present</i>              | Test 1 | >5.0  | >5.0                             | >5.0                 | None                    |
|                             | Test 2 |   | $\geq$ 5.0                       | >5.0                 | None                    |

Remarks - Results

None.

CONCLUSION

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

TEST FACILITY

BSL Bioservice (2002)

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