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

**FULL PUBLIC REPORT**

**Tego Wet 500**

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**Director  
NICNAS**

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## **FULL PUBLIC REPORT**

|                     |
|---------------------|
| <b>Tego Wet 500</b> |
|---------------------|

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

APPLICANT(S)

International Sales & Marketing Pty Ltd (ABN 36 467 259 314)

260 - 262 Highett Road

HIGHETT VICTORIA 3190

NOTIFICATION CATEGORY

Limited: Polymer with NAMW < 1000 (maximum 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, CAS Number, Structural Formula, Molecular Formula, Identity and Composition of Polymer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Partition Coefficient; Hydrolysis as a Function of pH; Adsorption/Desorption; Flammability Limits; Autoignition Temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

TSCA 1999 (USA) and DSL 1999 (Canada)

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

OTHER NAME(S)

Alcohol, alkoxylated

MARKETING NAME(S)

Tego Wet 500; LA 409

METHODS OF DETECTION AND DETERMINATION

|         |   |
|---------|---|
| Remarks | The notified polymer is a complex reaction product and there are no specific methods relating to its detection and determination. However, GC, MALDI-MS, IR, <sup>1</sup> H-NMR and <sup>13</sup> C-NMR data were provided. |
|---------|---|

### **3. COMPOSITION**

DEGREE OF PURITY

99.6 %

ADDITIVES/ADJUVANTS

None

DEGRADATION PRODUCTS

None known

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES  
None known

#### 4. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be imported as a raw material by ISM Australia.

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

| <i>Year</i>   | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>5</i> |
|---------------|----------|----------|----------|----------|----------|
| <i>Tonnes</i> | 1        | 1        | 1        | 1        | 1        |

##### USE

The notified polymer will be used industrially as a low foaming wetting agent in coatings, paints, and printing inks at concentrations  $\leq 2\%$ .

Inks (flexographic and gravure printing processes) will be used on printed materials that may include food packaging, wrapping paper, furniture laminates, paneling and magazines. It is estimated that 30% of the imported product will be used for such applications.

Coatings and paints may be used on timber products, furniture coatings, automotive coatings, anti-corrosion coatings, electro-deposition coatings, etc. It is estimated that 70% of the imported product will be used for such applications.

#### 5. PROCESS AND RELEASE INFORMATION

##### 5.1. Distribution, transport and storage

###### PORT OF ENTRY

Melbourne and Sydney by sea.

###### IDENTITY OF MANUFACTURER/RECIPIENTS

Following importation into Australia, the notified polymer will be stored at a third party warehouse contractor in Melbourne and Sydney for distribution as required to companies that manufacture paints, printing inks and surface coatings.

###### TRANSPORTATION AND PACKAGING

The notified polymer will be transported by road to the end user(s) in 25 kg and 200kg plastic drums, shrink-wrapped onto pallets.

##### 5.2. Operation description

###### *Reformulation*

Drums containing the notified polymer will be transferred from the storage area to the reformulation area using a forklift. During reformulation of the notified polymer into final products, one worker will weigh out an appropriate quantity of the notified polymer on a set of scales and then pour the notified polymer into the mixing vat. Pouring will be done manually when using 25kg pack sizes, or with a drum lifter when using 200kg drums. It is then combined with other ingredients and mixed in an open mixing vat. QC samples are taken from the vat during the final stages of the batch production by dipping a sample bottle into the mixer. The final mixture is pumped into 200 litre storage containers or packaged into pails (10 – 20L) through automated filling heads from the mixer. Final ink products will be automatically filled into ink cartridges. Final products contain the notified polymer at concentrations  $\leq 2\%$ .

###### *End use*

In printing ink applications, cartridges containing the finished products are linked to a printing press through an automated dosing device that delivers the product to the printing head.

Coatings and paints may be applied using rollers (eg. on timber flooring), or by spraying (eg. for automotive coatings).

### 5.3. Occupational exposure

#### *Number and Category of Workers*

| <i>Category of Worker</i>                        | <i>Number</i> | <i>Exposure Duration</i> | <i>Exposure Frequency</i> |
|--|---------------|--------------------------|---------------------------|
| Warehouse Operator                               | 3             | One hour per day         | 8 times per year          |
| Factory Worker (Formulation setup, concentrated) | 2             | Half hour per day        | 8 times per year          |
| Factory Worker (Formulation, diluted)            | 1             | Three hours per day      | 8 times per year          |
| Packers  | 2             | Half an hour per day     | 8 times per year          |
| Quality Control                                  | 1             | Half an hour per day     | 16 times per year         |
| End users  | 10            | Six hours per day        | 100 times per year        |

#### *Exposure Details*

##### *Reformulation*

Exposure of workers to the notified polymer (at concentrations ~100%) during transport and storage will only occur in the event of an accidental spillage. Workers will wear appropriate protective clothing during these operations.

There is potential for dermal and ocular exposure to the undiluted form of the notified polymer when weighing and pouring into the mixing vat for reformulation. Exposure to the notified polymer may also occur during mixing. However, exposure should be minimised by the local exhaust extraction devices fitted to the mixers and the personal protective equipment worn by workers such as masks, gloves, safety glasses and protective industrial clothing. Dermal and ocular exposure that may occur during QC sampling and transfer of the final product into storage containers or packaging containers should be minimised by similar means.

##### *End use*

During end use applications, the notified polymer will be present at a maximum concentration of 2%.

When used in printing applications, dermal exposure to the notified polymer may occur for a short duration during setup and changeover of printer cartridges. However, exposure should be minimised by workers wearing gloves and eye protection during direct handling procedures.

During roller application of the coatings and paints (approximately 50% of import volume) to timber products, furniture coatings, etc, dermal and ocular exposure to the notified polymer may occur. Exposure may be reduced by working in well ventilated areas, and/or by wearing personal protective equipment such as vapour masks.

During spray application of the coatings and paints (approximately 20% of import volume), mainly for automotive applications, dermal, ocular and inhalation exposure may occur. Exposure should be reduced by using mechanical ventilation and personal protective equipment such as coveralls and breathing protection.

### 5.4. Release

#### RELEASE OF CHEMICAL AT SITE

The product is reformulated into the final products in Australia. Assuming that the mixer will have approximately 1% (< 10 kg per annum) loss during filling, this would be washed to the waste water pit (it is expected that this will be done in approximately 70 batches with 150 g for each batch). The waste water washings are expected to be treated prior to release to sewer, resulting in even lower amounts of the notified polymer being released to sewer.

It is expected that less than 1% (< 10 kg per annum) of the notified polymer will be left in import drums after use. Drums would be left to dry with the product forming an inert polymeric layer prior to disposal via a licensed waste disposal operator. Direct release to soil should only occur from accidental release and is expected to be minimal.

#### RELEASE OF CHEMICAL FROM USE

It is estimated that 70% (< 700 kg per annum) of the notified polymer will be used as a wetting agent in coatings and paints. The products will dry to a polymeric layer and hence the polymer is not expected to be released to the environment. Used drums are likely to contain approximately 1% residue (< 7 kg per annum) of notified polymer and are allowed to dry to an inert polymeric film before being disposed of by authorised landfill. Any spillage is to be cleaned up immediately and not allowed to enter waterways or soil. The products are applied largely by roller application (50-70% of import quantity; maximum between 500-700 kg per annum), and some (<20%; <200 kg) may be applied by spraying. Given that the roller can contain 200 g of the product, this equates to up to 4 g of Tego Wet 500 per cleanup session (which would be washed in an appropriate location of the site). Assuming that clean up occurs a maximum of five times per 20 L drum of final product then a wastage rate of 5% results. This equates to a maximum of 35 kg per annum of the notified polymer. As the product is expected to be used by professionals, the washings are expected to be recovered, to the extent practicable, for licensed liquid waste disposal. The remainder is expected to be disposed of on-site, or to sewer, ensuring that no run-off to natural or storm waterways occurs.

For spray applications (< 200 kg per annum), the product may be used in both automotive and industrial applications. During application of coatings and paints by spraying, overspray is expected to account for approximately 35% (< 70 kg per annum). Although overspray for new automobiles (using robotic sprayers) is expected to be less, there is no indication as to whether the polymer will be used in this type of application. Overspray is expected to be collected on newspaper or be captured in spraybooth washings. Coatings and paints collected on newspaper are expected to be disposed of to landfill. Captured overspray containing the notified polymer, from spraybooths is expected to be disposed of by licensed contractor. It is expected that minimal amounts of coating and paint containing notified polymer (<1%; 0.7 kg) would be released to sewer from spraybooth traps. A small amount (5%; < 10 kg) is also expected to be wasted from cleaning of equipment. As the product is expected to be used by professionals, most washings are likely to be collected for disposal on newspaper or flushed to spraybooth traps. Assuming that at most half of the washings are released to sewer then this amounts to a maximum of 5 kg of the notified polymer. If 20% of the notified polymer is used in spray applications and 50% in roller applications then a maximum of 31 kg of notified polymer is expected to be released to sewer. This is comparable with the entire amount of notified polymer being used in roller applications where a maximum of 35 kg is expected to be released to sewer.

The remaining 30% (< 300 kg per annum) will be used as a wetting agent in inks. The inks will be used in many applications, including printed paper products. Assuming that approximately 50% (< 150 kg per annum) will be used in paper products then approximately half (NOLAN-ITU, 2001) will enter the paper recycling process. This will mean that up to 75 kg per annum will be disposed of to sewer. The remaining products (both paper and others) are likely to be disposed of to landfill or possibly incinerated at the end of their useful lives.

#### **5.5. Disposal**

Any waste neat product is likely to be disposed of through approved facilities by incineration. Companies recycling containers are likely to ensure that all residues are removed and allowed to dry to prevent liquid spillage before reuse or recycling. As the notified polymer is used in a paint, coating or printing ink, its disposal will share the same fate as the products in which the paint, coating or ink is incorporated. The majority will be disposed of to landfill or possibly incinerated at the end of the useful lives of the products; however, some will be disposed of to sewer from recycling of paper products and cleanup from paint and coating applications.

#### **5.6. Public exposure**

Products containing the notified polymer will be used industrially and will not be sold to the public. The public may come into contact with the notified polymer during use of products that have been coated or printed with coatings, paints or inks containing the notified polymer eg. food packaging, furniture, magazines, wrapping paper, etc. However, on such products the notified polymer is bound within a matrix after curing and will not be bioavailable. Therefore, exposure to the public is expected to be low.

## 6. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance at 20°C and 101.3 kPa** Clear, colourless liquid

**Melting Point** Extrapolated onset temperature: -43°C;  
Peak temperature: -39 °C

METHOD EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.  
Remarks Differential scanning calorimetry. Statement of GLP.  
TEST FACILITY AQura GmbH (2005a)

**Boiling Point** Extrapolated onset temperature: 339°C;  
Peak temperature: 372-373 °C at 100.9 kPa

METHOD EC Directive 92/69/EEC A.2 Boiling Temperature.  
Remarks Differential scanning calorimetry. Statement of GLP.  
TEST FACILITY AQura GmbH (2005a)

**Density** 940-980 kg/m<sup>3</sup> at 25°C

METHOD DIN 51757  
Remarks Cited in MSDS

**Vapour Pressure** 0.14 kPa at 20°C

METHOD OECD TG 104 Vapour Pressure.  
EC Directive 92/69/EEC A.4 Vapour Pressure.  
Remarks Static method. Statement of GLP.  
TEST FACILITY AQura GmbH (2005b)

**Water Solubility** 1.16 g/L at 25 ± 0.5°C

METHOD Similar to the preliminary test of OECD TG 105 Water Solubility guidelines.  
Remarks Flask Method. Aliquots of 110, 125, 250, and 500 mg of test substance were added to 100 g of water. Only the 110 mg sample remained clear. A further two solutions of 110 mg/L were prepared. Test substance was then added to these solutions in a drop-wise manner until the solutions were turbid. The solutions were stirred for a further 72 hours and remained turbid. The solutions were weighed at 24, 48 and 72 hours and the solubility calculated. All three test results were 1.16 g/L. The MSDS reports water solubility as 1 – 10 g/L at 25°C.  
TEST FACILITY Goldschmidt Analytical Laboratory (2001)

**Hydrolysis as a Function of pH** Not tested

Remarks The notified polymer contains no functional groups likely to undergo hydrolysis in the environmental pH range of 4 - 7. However, the functional groups may undergo cleavage under very acidic conditions at high temperatures.

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

Remarks The notified polymer is surface active and emulsifies the octanol and water. No clear phase separation of the octanol and water occurs. The test is therefore not applicable.

**Adsorption/Desorption** Not determined  
– screening test

Remarks The notified polymer contains both hydrophilic and hydrophobic portions within the molecule. The hydrophobic portion is expected to adsorb to the organic carbon in soil.



|                                 |  |
|---------------------------------|--|
| <b>Dissociation Constant</b>    | Not determined   |
| Remarks                         | The notified polymer contains no ionisable functional groups.  |
| <b>Flash Point</b>              | 157 ± 0.5°C at 101.3kPa  |
| METHOD                          | EC Directive 92/69/EEC A.9 Flash Point (closed cup).   |
| Remarks                         | Determined using the Pensky-Martens method (closed cup). Statement of GLP. The notified polymer is classified as a C2 combustible liquid according to NOHSC <i>National Standard for the Storage and Handling of Workplace Dangerous Goods</i> (NOHSC 2001). |
| TEST FACILITY                   | AQura GmbH (2005c)   |
| <b>Flammability Limits</b>      | Not determined.  |
| Remarks                         | Based on the flash point the notified polymer is not classified as flammable according to the Australian Dangerous Goods classification (FORS, 1998)   |
| <b>Autoignition Temperature</b> | Not determined.  |
| Remarks                         | The autoignition temperature will be > 157°C, based on its flash point.  |
| <b>Explosive Properties</b>     | Not predicted to be explosive.   |
| Remarks                         | Test not conducted. From examination of the structure, there are no chemical groups that would infer explosive properties.   |
| <b>Reactivity</b>               |  |
| Remarks                         | The notified polymer is expected to be stable under normal conditions of use.  |
| <b>Viscosity</b>                | 150 mPas at 25°C   |
| Remarks                         | Test report not available  |

## 7. TOXICOLOGICAL INVESTIGATIONS

| <i>Endpoint and Result</i>          | <i>Assessment Conclusion</i> |
|-------------------------------------|------------------------------|
| Rat, acute oral LD50 >2000 mg/kg bw | low toxicity                 |
| Rabbit, skin irritation             | non-irritating               |
| Rabbit, eye irritation              | slightly irritating          |

### 7.1. Acute toxicity – oral

|                  |  |
|------------------|--|
| TEST SUBSTANCE   | Notified polymer   |
| METHOD           | OECD TG 401 Acute Oral Toxicity – Limit Test.                |
| Species/Strain   | Rat/Sprague-Dawley (Albino)                                  |
| Vehicle          | Test substance administered as supplied (purity not stated). |
| Remarks - Method | No significant protocol deviation.                           |

#### RESULTS

| <i>Group</i> | <i>Number and Sex<br/>of Animals</i> | <i>Dose<br/>mg/kg bw</i> | <i>Mortality</i> |
|--------------|--------------------------------------|--------------------------|------------------|
| 1            | 5/sex                                | 2000                     | 0                |

|                   |   |
|-------------------|---|
| LD50              | > 2000 mg/kg bw   |
| Remarks - Results | No animals died during the observation period of 15 days.<br>No pathological findings noted.<br>All rats had an increase in body weight during the 15 day observation period. |

|            |   |
|------------|---|
| CONCLUSION | The notified polymer is of low toxicity via the oral route. |
|------------|---|

|               |                      |
|---------------|----------------------|
| TEST FACILITY | BioChem GmbH (1997a) |
|---------------|----------------------|

### 7.4. Irritation – skin

|                    |  |
|--------------------|--|
| TEST SUBSTANCE     | Notified polymer   |
| METHOD             | OECD TG 404 Acute Dermal Irritation/Corrosion.   |
| Species/Strain     | Rabbit/albino  |
| Number of Animals  | 3 male   |
| Vehicle            | Test substance administered as supplied (purity not stated).   |
| Observation Period | 9 days   |
| Type of Dressing   | Occlusive  |
| Remarks - Method   | No significant protocol deviation.<br>A sample of 0.5ml of test substance was applied undiluted to the skin of each animal. After 4 hours the test substance was removed and the animal was observed for an additional 9 days. |

#### RESULTS

| <i>Lesion</i>   | <i>Mean Score*<br/>Animal No.</i> |   |   | <i>Maximum<br/>Value</i> | <i>Maximum Duration<br/>of Any Effect</i> | <i>Maximum Value at End<br/>of Observation Period</i> |
|-----------------|-----------------------------------|---|---|--------------------------|---|---|
|                 | 1                                 | 2 | 3 |                          |   |   |
| Erythema/Eschar | 0                                 | 0 | 0 | 0                        | 0   | 0   |
| Oedema          | 0                                 | 0 | 0 | 0                        | 0   | 0   |

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

|                   |  |
|-------------------|--|
| Remarks - Results | Under the conditions of this experiment, the notified polymer did not produce any acute systemic toxicological signs or mortality. All rabbits |
|-------------------|--|

showed a gain in body weight during the experiment.

CONCLUSION

The notified polymer is non-irritating to the skin.

TEST FACILITY

BioChem GmbH (1997b)

## 7.5. Irritation – eye

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain

Rabbit/Albino

Number of Animals

3 female

Observation Period

8 days

Remarks - Method

No significant protocol deviation.

The test substance was applied in a single dose of 0.1mL into the conjunctival sac of the right eye of each rabbit. After 24hr, the test substance was removed with saline solution. The other eye remained untreated and served as a reference control.

Conjunctival discharge was not evaluated in this study.

RESULTS

| <i>Lesion</i>                 | <i>Mean Score*</i><br><i>Animal No.</i> |     |     | <i>Maximum Value</i> | <i>Maximum Duration of Any Effect</i> | <i>Maximum Value at End of Observation Period</i> |
|-------------------------------|---|-----|-----|----------------------|---------------------------------------|---|
|                               | 1                                       | 2   | 3   |                      |                                       |   |
| <i>Conjunctiva: redness</i>   | 1.7                                     | 1.5 | 1.7 | 2.5                  | 3 d                                   | 0   |
| <i>Conjunctiva: chemosis</i>  | 1.3                                     | 1.3 | 2.3 | 3                    | 3 d                                   | 0   |
| <i>Conjunctiva: discharge</i> | -                                       | -   | -   | -                    | -                                     | -   |
| <i>Corneal opacity</i>        | 0.3                                     | 0   | 0.3 | 1                    | 2 d                                   | 0   |
| <i>Iridial inflammation</i>   | 0                                       | 0   | 0   | 0                    | 0                                     | 0   |

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

Remarks - Results

Under the conditions of this experiment, the notified polymer did not produce any acute systemic toxicological signs or mortality.

After evaluation of the eye reaction, all three rabbits developed hyperaemic blood vessels. This effect was estimated at grade 0.5 to 2.5. This effect was estimated at grade 1 to 3. Two rabbits showed opacity of the cornea 48 hours after application. This effect was estimated at grade 1. Ocular lesions of iris could not be observed during the study. All lesions were completely reversible within 4 days.

CONCLUSION

The notified polymer is moderately irritating to the eye.

TEST FACILITY

BioChem GmbH (1997c)

## 8. ENVIRONMENT

### 8.1. Environmental fate

#### 8.1.1. Ready biodegradability

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 301 D Ready Biodegradability: Closed Bottle Test.

Inoculum

Sewage sludge

Exposure Period

28 Days

Auxiliary Solvent

None

Analytical Monitoring  
Remarks - Method

Oxygen Meter

Sewage sludge from municipal sewage plant Karlsruhe/Neurent was used for the test. Duplicate analyses were performed on four different nominal concentrations (0.69, 1.38, 2.76 and 4.14 mg/L) of test substance, with inoculum and nutrient solution. Two further duplicate blank tests were conducted, one with nutrient only and the other with inoculum and nutrient. Two reference materials (sodium acetate (NaAc) and potassium hydrogen phthalate (KH phthalate) were tested in duplicate as well as a toxicity test using sodium acetate, inoculum and test substance. The tests were conducted in airtight and dark conditions at  $22 \pm 2^\circ\text{C}$ . The chemical oxygen demand (COD) was determined by testing four samples of notified substance at a concentration of 211.6 mg/L (in purified water).

## RESULTS

| <i>Test substance</i> |                      | <i>NaAc</i> |                      | <i>KH phthalate</i> |                      |
|-----------------------|----------------------|-------------|----------------------|---------------------|----------------------|
| <i>Day</i>            | <i>% Degradation</i> | <i>Day</i>  | <i>Degradation %</i> | <i>Day</i>          | <i>Degradation %</i> |
| 7                     | 3.9                  | 7           | 71.2                 | 7                   | 72.6                 |
| 14                    | 1.8                  | 14          | 68.6                 | 14                  | 75.1                 |
| 21                    | 4.7                  | 21          | 76.3                 | 21                  | 71.3                 |
| 28                    | 8.2                  | 28          | 80.5                 | 28                  | 80.9                 |

Remarks - Results

The COD was 2.23 g O<sub>2</sub>/g of test substance. The biological degradation was calculated from the biological oxygen demand (BOD) as compared with the COD. The toxicity test showed 88.5% degradation of NaAc which was higher than the NaAc alone and means that the test substance did not inhibit the inoculum. The maximum oxygen depletion of the blanks was 0.5 mg O<sub>2</sub>/L (the limit for a valid test is 1.5 mg O<sub>2</sub>/L). Both reference substances exceeded the minimum degradation for a valid test.

CONCLUSION

The test substance is not considered readily biodegradable.

TEST FACILITY

BioChem GmbH (1998a)

### 8.1.2. Bioaccumulation

Not tested. The notified polymer is water soluble and is therefore unlikely to bioaccumulate.

## 8.2. Ecotoxicological investigations

### 8.2.1. Acute toxicity to fish

TEST SUBSTANCE

Notified polymer

METHOD

OECD TG 203 Fish, Acute Toxicity Test – static test.

Species

*Brachydanio rerio* (Zebra fish)

Exposure Period

96 h

Auxiliary Solvent

None

Water Hardness

200 mg CaCO<sub>3</sub>/L

Analytical Monitoring

HPLC; Visual observation

Remarks – Method

Ten fish were subjected to single tests of nominal concentrations of test substance (as detailed below) and a control. Dead fish were removed when observed.

Length of fish: 2.5-3.7 cm

Light: 16 h light; 8 h dark

Temperature 22.5 – 23.2°C

Dissolved oxygen: 8.5 – 9.1 mg/L

pH 7.76 – 7.86

## RESULTS

| Concentration mg/L |               |                | Number of Fish | Mortality |      |      |      |      |
|--------------------|---------------|----------------|----------------|-----------|------|------|------|------|
| Nominal            | Actual<br>0 h | Actual<br>96 h |                | 3 h       | 24 h | 48 h | 72 h | 96 h |
| Control            | < 0.5         | < 0.5          | 10             | 0         | 0    | 0    | 0    | 0    |
| 13.2               | 10.4          | 8.5            | 10             | 0         | 0    | 0    | 0    | 0    |
| 19.8               | 16.9          | 13.1           | 10             | 0         | 0    | 0    | 0    | 0    |
| 29.6               | 25.6          | 20.0           | 10             | 0         | 0    | 0    | 0    | 0    |
| 44.4               | 41.4          | 36.0           | 10             | 9         | 10   | 10   | 10   | 10   |
| 66.7               | 65.6          | 61.2           | 10             | 10        | 10   | 10   | 10   | 10   |
| 100.0              | 100.4         | 93.7           | 10             | 10        | 10   | 10   | 10   | 10   |

LC50 36.3\* mg/L (nominal) and 26.8\* mg/L (measured) at 96 hours.

LOEC 29.6 mg/L (nominal) and 20.0 mg/L (measured) at 96 hours.

Remarks – Results Test solutions were clear with no observed undissolved test substance. Fish in the 29.6 and 44.4 mg/L test concentrations showed abnormal behaviour including intensive respiration movements, uncontrolled movements and loss of equilibrium.

\*The LC50 values were calculated from the geometric mean of two results.

CONCLUSION The notified polymer is harmful to fish.

TEST FACILITY BioChem GmbH (1998b)

### 8.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified polymer

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum Activated sludge

Exposure Period 3 hours

Concentration Range Nominal: 1.88 - 30 mg/L

Remarks – Method Sewage sludge from municipal sewage plant Karlsruhe/Neurent was used for the test. Sewage sludge and feed were exposed to test concentrations of 1.88, 3.75, 7.5, 15, and 30 mg/L of test substance. Three test concentrations (10, 25 and 50 mg/L) of 3,5 dichlorophenol were run as a reference, as well as two controls. The oxygen consumption of the test substance was compared with the controls. Temperature 20.3 – 22.6°C.

## RESULTS

IC50 No Inhibition Observed

NOEC No Inhibition Observed

Remarks – Results The EC50 of the reference material was 19.36 mg/L, which is within the acceptable range of 5 – 30 mg/L. The test concentrations showed an increase in respiration of up to 23.3%.

CONCLUSION Not inhibitory to microbial activity at up to 30 mg/L.

TEST FACILITY BioChem GmbH (1998c)

## 9. RISK ASSESSMENT

### 9.1. Environment

#### **9.1.1. Environment – exposure assessment**

The vast majority of the notified polymer will be used in inks and paints. The notified polymer is likely to eventually degrade in-situ on the items to which it is applied or it will share the same fate as the items to which it is applied. Most of these items will be disposed of to landfill at the end of their useful lives. The notified polymer is expected to remain with the cured paint or ink and eventually undergo in-situ degradation to landfill gases including methane, oxides of carbon; and water vapour.

A small amount (< 75 kg per annum) is likely to be released to sewer from recycling of printed paper material. A further amount (< 35 kg per annum) will also require disposal from cleanup of spray and roller applications of paint. Although professional painters are unlikely to release this entire amount to sewer and at least some of the notified polymer will adsorb to sludge or degrade in the sewage treatment plant, if a worst case scenario is assumed, then a total of 110 kg of the notified polymer will be released from sewage systems throughout Australia over 260 working days. The predicted environmental concentration (PEC) at sewage outfall is therefore 0.10 µg/L ( $110 \text{ kg} \div (20.5 \text{ million persons} \times 200 \text{ L per person per day} \times 260 \text{ working days})$ ).

#### **9.1.2. Environment – effects assessment**

Ecotoxicity tests were performed on only one aquatic species (fish). The predicted no effect concentration may be calculated from the LC50 of this single test (26.8 mg/L – actual) and applying a safety factor of 1000. The PNEC is calculated as 26.8 µg/L.

#### **9.1.3. Environment – risk characterisation**

The risk quotient (RQ) for the notified polymer in the aquatic environment at sewage outfall is calculated by dividing the PEC (0.10 µg/L) by the PNEC (26.8 µg/L). The resulting RQ is <0.01. The notified polymer is therefore unlikely to pose an unacceptable risk to the aquatic environment based on the notified use pattern.

### **9.2. Human health**

#### **9.2.1. Occupational health and safety – exposure assessment**

The concentration of the notified polymer in the imported product is ~ 100%. Exposure to the notified polymer is unlikely to occur during transport, except in the event of an accident that results in a breach of packaging. Dermal or ocular exposure to the notified polymer may occur during reformulation into final products, particularly during manual transfer of the imported product into the blending vessel and during mixing. However, worker exposure should be reduced by local exhaust ventilation and the use of personal protective equipment. Overall, exposure to the notified polymer during reformulation is expected to be low.

In end use products, the notified polymer will be present at concentrations  $\leq 2\%$ . When used in printing inks, dermal exposure to the notified polymer is expected to be low due to automation of the dosing device used to deliver the product to the printing head. In addition, the wearing of personal protective equipment when handling the product directly may further lower exposure.

When used in paints and coatings, dermal, ocular and inhalation exposure to the notified polymer may occur during roller and spraying applications. Protective measures are likely to vary widely depending on the type of product in which the notified polymer is contained (water based or solvent based), the surface to which it is applied, and the application site. The notifier has stated that protective measures may include mechanical ventilation, and personal protective equipment such as vapour masks, breathing protection, protective clothing, etc. The low concentration of the notified polymer in final products ( $\leq 2\%$ ) may mitigate concerns associated with worker exposure to the notified polymer during end use application.

#### **9.2.2. Public health – exposure assessment**

The notified polymer is present in a number of products that the public are likely to come into contact with occasionally, such as timber products, furniture, food packaging, wrapping paper, magazines, etc. However, the notified polymer is unlikely to be bioavailable as it becomes encapsulated within a polymer matrix during curing. Therefore the level of public exposure is

expected to be minimal.

#### **9.2.3. Human health – effects assessment**

The notified polymer was of low acute oral toxicity in rats (LD50 > 2000 mg/kg bw). It was found to be non-irritating to the skin of rabbits, and moderately irritating to the eyes of rabbits, though not meeting the criteria for classification as an eye irritant.

Based on the available data, the notified polymer can not be classified under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

The Health Canada assessment summary states that the notified polymer contains ethylene glycol ethers that constitute a structural alert. Short chain ethylene glycol ethers have been associated with a number of health effects, including haemolysis, bone marrow damage, direct and indirect kidney damage, liver damage, immunotoxicity, central nervous system depression, leukopenia of lymphocytes and granulocytes, and developmental and reproductive toxicity. In addition, short chain ethylene glycol ethers are absorbed by all routes of exposure and cause irritation of skin, eyes and mucous membranes.

#### **9.2.4. Occupational health and safety – risk characterisation**

The data provided suggest that the notified polymer is of low acute oral toxicity, is not irritating to skin, and causes moderate eye irritation in animals. However, it does not meet the criteria for classification. There is an indication that the presence of ethylene glycol ethers within the notified polymer may potentially cause significant health concerns, including damage to the liver, bone marrow, and kidneys, haemolysis, central nervous system depression, as well as developmental and reproductive toxicity.

There is potential for uptake following dermal exposure to the notified polymer, given its relatively low molecular weight, the significant proportion of low molecular weight species, and its physical/chemical properties (European Commission, 2003).

The risk of eye irritation exists when handling the imported products containing ~100% of the notified polymer, particularly during weighing and transfer into the blending vessel when reformulating into final products. The risk also exists during end use of the products containing ≤ 2% of the notified polymer, particularly during painting and coating applications. However, the risk should be minimised by either the short exposure duration to the imported product containing 100% of the notified polymer, or the relatively low concentration of the notified polymer in the end products (≤ 2%). In addition, the use of local exhaust ventilation and PPE, such as eye protection, gloves and protective clothing will further reduce the risk. Spraying applications should only take place under local exhaust ventilation and workers should wear respirators.

There is the potential for skin absorption and adverse effects associated with the functional group of concern. However, there is no indication that the notified polymer is likely to pose a significant health risk to workers based on the available toxicological information, and the low potential for worker exposure. A number of workplace control measures will be recommended to ensure the safe use of the notified polymer.

#### **9.2.5. Public health – risk characterisation**

When present in consumer products, the notified polymer will be encapsulated within a polymer matrix and will not be bioavailable. As such, the risk of adverse effects to the public is considered to be minimal.

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

#### **10.1. Hazard classification**

Based on the available data the notified polymer can not be classified under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

As a comparison only, the classification of 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> |
|--|------------------------|-------------------------|
| Acute hazards to the aquatic environment | 3                      | Harmful to aquatic life |

## 10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:

The polymer 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 no significant 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 the notified polymer 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 the notified polymer 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

### CONTROL MEASURES

#### Hazard Classification and Labelling

#### Health Surveillance

- As the notified polymer may be of health concern, employers should carry out health surveillance for workers involved in handling of the notified polymer.

#### Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
  - Local exhaust ventilation during reformulation and packaging.
  - Ventilation during paints and coating operations.
  - Local exhaust ventilation should be in place during all spraying operations.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid skin, eye and inhalation exposure.



- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
  - Safety glasses, gloves and protective industrial clothing during reformulation and when products are applied using roller
  - Respiratory protection, safety glasses, gloves, and protective industrial clothing during spraying operations.

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.
- The notified polymer should be handled in accordance with provisions of State and Territory legislation regarding the Handling of Combustible and Flammable Liquids.
- 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

#### Disposal

- The notified polymer should be disposed of by authorised incineration or landfill.

#### Storage

- The notified polymer should be stored in accordance with provisions of State and Territory legislation regarding the Storage of Combustible and Flammable Liquids.

#### Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, whilst preventing entry to drains and waterways. Do not discharge to soil or subsoil. Collect spill with adsorbent material (eg sand, vermiculite or universal binder) and place in suitable containers for disposal.

### 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
  - the introduction volume exceeds one tonne per annum notified polymer; or
  - the concentration of the notified polymer in final products exceeds 2%; or
  - repeat dose toxicity and/or developmental/reproductive toxicity data becomes available; or
  - reporting of adverse health effects becomes available.

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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