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July 2010

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

**FULL PUBLIC REPORT**

**Humic acids, sulfomethylated, sulfonated, potassium salts**

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, Water, Heritage and the Arts.

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL: + 61 2 8577 8800	
FAX+ 61 2 8577 8888	
Website:	<a href="http://www.nicnas.gov.au">www.nicnas.gov.au</a>

**Director  
NICNAS**

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**FULL PUBLIC REPORT****Humic acids, sulfomethylated, sulfonated, potassium salts****1. APPLICANT AND NOTIFICATION DETAILS**

## APPLICANT(S)

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

## 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: other names, molecular weight, polymer constituents, residual monomers/impurities, use details, import volume and site of manufacture/reformulation.

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

Variation to the schedule of data requirements is claimed as follows: partition coefficient, adsorption/desorption and dissociation constant.

## PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

## NOTIFICATION IN OTHER COUNTRIES

United States of America (2000)  
Canada (1998)

**2. IDENTITY OF CHEMICAL**

## MARKETING NAME(S)

BorreGRO HA-1

## CAS NUMBER

1214752-66-5

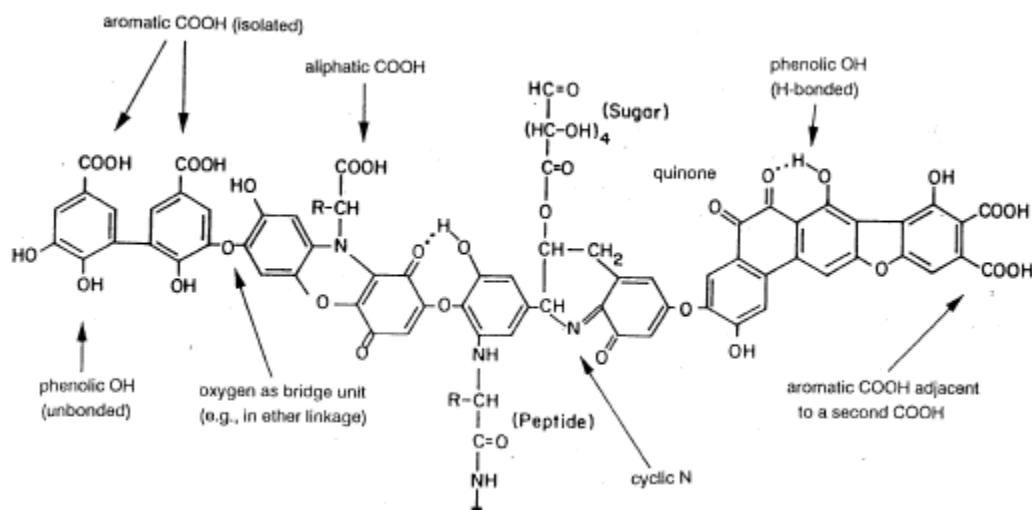
## CHEMICAL NAME

Humic acids, sulfomethylated, sulfonated, potassium salts

## MOLECULAR FORMULA

Unspecified

## STRUCTURAL FORMULA



Hypothetical structure of humic acid from Stevenson (1994).

## MOLECULAR WEIGHT

$$> 1,000 \text{ Da}$$

ANALYTICAL DATA

Reference IR, UV and proton-induced X-ray emission (PIXE) spectra were provided.

### 3. COMPOSITION

DEGREE OF PURITY &gt; 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS	None
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ADDITIVES/ADJUVANTS	None
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## 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Black powder

Property	Value	Data Source/Justification
Melting Point	Not determined	Decomposes prior to melting
Density	550 kg/m <sup>3</sup> (powder bulk density)	MSDS
Vapour Pressure	$< 1.3 \times 10^{-9}$ kPa	Estimated based on the NAMW > 1,000 Da (US EPA, 2007)
Water Solubility	> 980 g/L at 65°C	Measured for insolubles.
Hydrolysis as a Function of pH	Not determined	The notified polymer does not contain any readily hydrolysable functional groups.
Partition Coefficient (toluene/water)	log P <sub>tw</sub> = -2.84 to -2.30	Measured for humic substances in a toluene/water system. The notified polymer is expected to exhibit surface active characteristics.
Adsorption/Desorption	Not determined	Humic acids sorb to positively charged mineral surfaces.
Dissociation Constant	Not determined	The notified polymer is a salt and is therefore expected to be ionised over the environmental pH range (4-9).
Particle Size	120 µm	Source not specified
Flash Point	Not determined	Polymer with a NAMW >1,000 Da
Flammability	Upper: 3.5%	MSDS

Autoignition Temperature	Lower: 0.2%	MSDS
Explosive Properties	400°C	The structural formula contains no
	Not expected to be explosive	explosophores

## DISCUSSION OF PROPERTIES

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

*Reactivity*

Stable under normal conditions of use.

**5. INTRODUCTION AND USE INFORMATION**

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

The notified polymer will be imported in to Australia and will not be manufactured in 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>	100-300	100-300	100-300	100-300	100-300

## PORT OF ENTRY

Melbourne

## IDENTITY OF MANUFACTURER/RECIPIENTS

Agricultural nutrient manufacturer in Victoria.

## TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 25 kg bags as the neat (> 90%) material.

## USE

The notified polymer will be used as a component of fertilisers.

## OPERATION DESCRIPTION

The notified polymer will not be manufactured in Australia, but will be reformulated after importation.

*Reformulation*

At customer blending sites, the notified polymer (at > 90%) will be formulated into fertilisers by mixing with water and various micronutrients. The bags containing the notified polymer will be poured into a mixing vessel (10,000 L) under local exhaust ventilation. When mixing is complete, the fertilisers containing the notified polymer at concentrations of 2 - 3 kg per 1000 L of water will be decanted into containers (20 L pails, 200 L drums and 1,000 L IBCs).

*End use*

The fertilisers containing the notified polymer at concentrations of 2 - 3 kg per 1000 L of water will be used only by commercial farming operations and will not be available to the public. The fertiliser containing the notified polymer will be applied by boom spray or crop irrigation systems at a rate of approximately 5 L per hectare (0.01-0.015 kg of notified polymer per hectare) and will be diluted prior to foliar application.

**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 (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Reformulation workers	4	4	24

## EXPOSURE DETAILS

*Reformulation*

There is potential for dermal, ocular and inhalation exposure to the notified polymer during reformulation. The greatest potential for exposure is during the transfer of the imported notified polymer (> 90%) in to the mixing vessels. Exposure will be limited by the use of local exhaust ventilation and the use of PPE such as gloves, goggles, protective clothing and dust masks. After reformulation is complete exposure to the notified polymer in the products containing it will be reduced by the low concentration ( $\leq 0.3\%$ ).

*End use*

Dermal, ocular and inhalation exposure to the notified polymer (at  $\leq 0.3\%$ ) is possible during the application of fertilisers containing it. Exposure should be reduced when overalls and gloves are worn by farmers.

**6.1.2. Public exposure**

The products containing the notified polymer will not be sold to the public. Therefore the public will only be exposed to the notified polymer in the event of accidental spill during transportation.

**6.2. Human health effects assessment**

The results from toxicological investigations conducted on the notified polymer or acceptable analogues of 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 Assessment Conclusion</i>
Rat, acute oral toxicity <sup>1</sup>	LD50 > 5,000 mg/kg bw; low toxicity
Rabbit, skin irritation <sup>1</sup>	slightly irritating
Rabbit, eye irritation <sup>1</sup>	slightly irritating
Repeat dose oral toxicity – 90 days <sup>2</sup>	NOAEL > 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation <sup>3</sup>	Non-mutagenic
Developmental and reproductive effects <sup>3</sup>	Non-teratogenic

<sup>1</sup> Notified polymer

<sup>2</sup> Humic acid or its sodium salts

<sup>3</sup> Humic acid

*Toxicokinetics, metabolism and distribution.*

Based on the high molecular weight ( $M_n > 1000$  Da), high water solubility (> 980 g/L at 65°C) and low partition coefficient ( $\log P_{ow} = -2.84$  to  $-2.30$ ), absorption across biological membranes is expected to be low. Systemic toxicity after dermal exposure to the notified polymer is therefore expected to be low. In the analogous chemical, humic acid, absorption across the isolated gastrointestinal tract of the rat ranged from 0.05 to 0.07% (EMA, 1999).

*Acute toxicity.*

The notified polymer is considered to be of low acute toxicity via the oral route based on tests conducted in rats. No acute inhalation toxicity data were provided for the notified chemical or its close analogues.

*Irritation and Sensitisation.*

Based on tests conducted in rabbits the notified polymer is considered to be slightly irritating to the skin and eye.

*Repeated Dose Toxicity.*

There were no repeated dose studies available on the notified polymer. However, studies on the analogous polymers (humic acid or its sodium salts) in rats (1000 mg/kg bw/day for 30 and 90 days), dogs (300 mg/kg bw/day for 90 days) and rabbits (1000 mg/kg bw/day for 90 days) reported no adverse effects (EMA, 1999).

*Mutagenicity.*

There are no mutagenicity studies available for the notified polymer. However, the analogous polymer humic acid was found to not be mutagenic using a bacterial reverse mutation test (Sato et al., 1986).

*Toxicity for reproduction.*

Tests on the analogous polymer humic acid in rats showed no teratogenic effects following oral and intraperitoneal application (Golbs et al., 1982).

**Health hazard classification**

Based on the data provided, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

**6.3. Human health risk characterisation****6.3.1. Occupational health and safety**

The notified polymer is slightly irritating to the skin and eyes and of low acute oral toxicity.

Irritation potential for reformulation workers is likely during the transfer of the imported notified polymer (> 90%) in to the mixing vessels. The expected use of PPE by these workers should reduce exposure levels and hence lower the incidence of irritation effects.

The particle size of the notified polymer (120 µm) indicates that a portion may be respirable. The notified polymer has a molecular weight < 10,000 Da and is water soluble and therefore if the notified polymer is inhaled at low levels, it is likely to be cleared from the upper respiratory tract readily through mucociliary action. Small proportions of the notified polymer may reach the lower respiratory tract, but it should still be readily cleared from the lungs unless high levels are inhaled. When high concentrations of the notified polymer are inhaled, it is likely to be cleared from the lungs, but this may be slower and temporary respiratory impairment is possible. The expected use of dust masks and local exhaust ventilation when handling the powdered notified polymer by reformulation workers should reduce inhalation exposure levels and hence lower the risk of temporary lung overloading.

Although farmers may be exposed to the notified polymer when handling fertilisers containing the notified polymer, exposure levels will be low given the low concentration of the notified polymer ( $\leq 0.3\%$ ) in fertilisers.

Overall, given the expected use of PPE and engineering controls by reformulation workers and the low concentration in the fertilisers, the risk to the health of workers by the notified polymer is not considered unacceptable.

**6.3.2. Public health**

The notified polymer or products containing it will not be sold to the public. Therefore the risk to the public from the notified polymer is not considered to be unacceptable.

**7. ENVIRONMENTAL IMPLICATIONS****7.1. Environmental Exposure & Fate Assessment****7.1.1 Environmental Exposure****RELEASE OF CHEMICAL AT SITE**

The imported notified polymer will be formulated into fertiliser in Australia. Engineering controls on the formulation equipment minimise release of the notified polymer during reformulation. Accidental spills during transport or formulation are likely to be collected and recycled or disposed of to landfill. Residues cleaned from the formulation equipment are stored in waste water tanks and reused. Notified polymer residue remaining in import containers are expected to be disposed of to landfill.

**RELEASE OF CHEMICAL FROM USE**

The notified polymer will be a component in fertilisers used by farmers. The fertiliser will be applied by boom spray or crop irrigation systems to soil and plants. Notified polymer residue remaining in product containers are expected to be disposed of to landfill.

**RELEASE OF CHEMICAL FROM DISPOSAL**

During use, all the notified polymer is expected to be applied to the soil as the fertiliser. Unused fertiliser is likely to be disposed of by an authorised waste disposal company.

**7.1.2 Environmental fate**

The notified polymer is derived from humic acid, a chemically stable and complex polymer that is a natural component of soil. Humates are produced from the breakdown of plant materials in the soil, and represent 20-30% of soil carbon (Skjemstad *et al.*, 1996). They do not rapidly biodegrade, as the  $^{14}\text{C}$ -labelled humic acid fraction was found to mineralise by 12.7% in a year, and was estimated to have a half life of 10 years when incubated in soil (Qualls, 2004). Humic acids exhibit surface active characteristics and participate in hydrophobic interactions due to the combination of a hydrophobic core with hydrophilic sidechains (Badun *et al.*, 2004). They sorb to mineral surfaces in soil and the extent of interaction depends on the mineral type and pH, however, humic acids sorb more strongly to positively charged minerals than negatively charged minerals (Spark *et al.*, 1997). Naturally present in the water column, humic acids comprise 40-90% of dissolved organic carbon in surface waters (Fox, 1990). Humic acid is considered an acceptable analogue for the notified polymer and thus the notified polymer is not expected to bioaccumulate due to its high molecular weight, low partition coefficient ( $\log P \leq -2.3$ , as determined for humic acid in a toluene-water system) and high water solubility. For the details of the environmental fate studies, refer to Appendix C.

### 7.1.3 Predicted Environmental Concentration (PEC)

Of the potential 300 tonnes of notified polymer imported, it can be assumed for the purpose of the risk assessment, that all of the notified polymer will be applied to soil as fertiliser. The recommended rate of application is up to 5 L/hectare (15 g of notified polymer/ha).

The recommended application rate of the fertiliser results in a worst case  $\text{PEC}_{\text{soil}}$  of approximately  $3.5 \mu\text{g C/kg}$  from the notified polymer in the top 15 cm of soil (since the notified polymer is persistent (EPHC, 2009)) and assuming a soil density of  $1500 \text{ kg/m}^3$ . In the majority of Australian topsoils the organic carbon content is 0.5% or greater (ANRA, 2001), and as humic acid represents 20-30% of the organic carbon, a conservative estimate of the carbon in the soil due to humic acid is  $1 \text{ g C/kg}$ . Therefore, the application of the fertiliser at the recommended rate will not significantly increase the background soil humate levels in carbon-poor soils. Even in the event of multiple applications and assuming there's no degradation of the notified polymer in the soil, it will require over 23 years of monthly applications to raise the background humic levels in carbon-poor soils by 0.1%.

Similarly, run-off of the fertiliser will not significantly increase background levels leached from the soil. Humic acids are naturally present in the water column, and clean water with a low organic carbon content ( $< 2 \text{ mg/L}$ ) contains a conservative background estimate of  $0.8 \text{ mg C/L}$  from humic acid. The concentration of humic acid in the worst case "edge of field" run-off water may be calculated by considering the amount of run-off water and amount of notified polymer on a hectare basis. Based on the Australian climate and catchment data, a rainfall event of 100 mm with 20 mm of run-off water is the worst case scenario. This will result in  $200 \text{ m}^3$  (200 000 L) of run-off water containing notified polymer. The resulting concentration of the notified polymer is  $(100 \div 100 \times 15 \text{ g/ha}) \div 200 \text{ 000 L} = 75 \mu\text{g notified polymer/L per hectare}$  or  $39.4 \mu\text{g C/L per hectare}$ . This amount only increases background humic levels in clean water by less than 5%. However, this increase is expected to be much less as it is a worst case scenario with respect to rainfall, and does not consider factors such as the topography of the land, the crops on the land, and the mobility of the notified polymer. Therefore, even multiple applications should not significantly increase the background humic levels.

With respect to spray drift and as a worst case scenario it is assumed that the fertiliser, applied at the recommended rate of 5 L/ha (15 g notified polymer/ha), is sprayed directly over a 15 cm standing body of clean water, resulting in a humic acid  $\text{PEC}_{\text{water}}$  of  $5.3 \mu\text{g C/L}$ . The  $\text{PEC}_{\text{water}}$  from one application is significantly less than the conservative humic acid concentration in clean water, and would require over 15 repeat applications directly over water to increase the background humic levels in clean water by 10%.

## 7.2. Environmental effects assessment

No ecotoxicity data were submitted. Anionic polymers are generally of low concern to the aquatic environment, and at pH 7 they usually exhibit low toxicity towards fish, with  $\text{LC}_{50}$  values  $> 100 \text{ mg/L}$ . However, anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. Whilst humates are known chelating agents, the toxicity to algae is likely to be reduced due to the presence of calcium ions in surface waters which will bind to the functional groups. It is also expected that the notified polymer would be present in surface waters in a chelated state after leaching through soil. The notified polymer, both in chelated and unchelated states, is likely to associate with soil, sludge and sediment and is therefore not expected to be bioavailable.



### 7.2.1 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) was not calculated as ecotoxicity data were not submitted and the notified polymer is expected to be of low concern to aquatic organisms (see Section 7.2).

### 7.3. Environmental risk assessment

The notified polymer is derived from humic acid, a complex polymer naturally occurring in soil and water. As it is an anionic polymer, it is likely to be of low concern to the aquatic environment. Any potential toxicity to algae is expected to be mitigated by the prevailing water hardness and becoming chelated after leaching through soil. Worst case scenario calculations based on direct overspray and run-off to a water body indicate that use of the notified polymer in fertiliser will not significantly increase the background levels of humates in the environment even after multiple applications. The calculations were compared to background humic estimates in carbon-poor soils and water with reduced organic carbon levels, which are minimum values for the Australian environment. Therefore, on the basis of its use pattern, the notified polymer is not expected to pose a risk to the environment.

## 8. CONCLUSIONS AND REGULATORY OBLIGATIONS

### Hazard classification

Based on the data provided, the notified polymer is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

### Human health risk assessment

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

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

### Environmental risk assessment

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

### Recommendations

#### CONTROL MEASURES

##### Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer when in the powdered form:
  - Local exhaust ventilation
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Avoid skin and eye contact when in the powder form
  - Avoid inhalation of dusts
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer when in the powdered form:
  - Respiratory protection (i.e. dust masks)
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

#### Disposal

- The notified polymer should be disposed of to landfill.
- Emergency procedures
- Spills or accidental release of the notified polymer should be handled by containment, collection and subsequent safe disposal.

### **Regulatory Obligations**

#### *Secondary Notification*

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

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

- (1) Under Section 64(1) of the Act; if
  - the 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 polymer has changed from a component of fertiliser applied as a liquid mixture/dilution, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 300 tonnes, 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 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

**Water Solubility** > 980 g/L at 65°C

Method	In-house Insolubles - Gravimetric test QC-045. Approximately 5 grams of powder solids of the notified polymer (moisture content determined) were transferred to 200 mL of distilled water at 65°C and stirred well. The material was filtered, dried, and weighed.
Remarks	The insolubles were found to be 0.07-0.66%. The notifier interpreted this result to represent the water solubility of the notified polymer as >98%, or >980 g/L.
Test Facility	Lignotech USA (1995)

**Partition Coefficient (n-octanol/water)** Log  $P_{tw}$  = -2.84 to -2.30

Method	The concentration of tritium labelled humic substances from peat and coal in a toluene/water system were determined by liquid scintillation counting.
Remarks	Humic acid exhibits surface active properties and participates in hydrophobic interactions due to its hydrophobic core and hydrophilic side chains. Hydrophobicity is usually measured in octanol/water systems, although other solvents can be used. The hydrophobicity of humic acid was measured in toluene/water which is the ideal system when concentrations are to be measured by scintillation counting. The toluene/water log partition coefficients for peat and coal humic acids were found to be -2.30 and -2.84, respectively. Humic acid is an acceptable analogue for the notified polymer and, therefore, the notified polymer is expected to have a low partition coefficient.
Test Facility	Badun <i>et al.</i> (2004).

**Adsorption/Desorption** Log  $K_{oc}$  not determined  
– screening test

Method	The interaction of humic acid with goethite, $\alpha$ -alumina, kaolinite and silica were studied with respect to the solubility of humic acid with pH. Interactions between the humic acid and the minerals was observed by proton release/uptake, as measured by potentiometric titrations.
Remarks	Humic acid was found to sorb to positively charged mineral surfaces to a greater extent than negatively charged mineral surfaces. The pH was found to affect solubility of humic acid and influence the extent of interaction.
Test Facility	Spark <i>et al.</i> (1997)

## APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

### B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified polymer (> 90%)
METHOD	US EPA Health Effects Test Guidelines OPPTS 870.1100 Acute Oral Toxicity, August 1998.
Species/Strain	Rat/Sprague-Dawley derived albino
Vehicle	Water
Remarks - Method	GLP compliant No significant protocol deviations

#### RESULTS

<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>
I	5 per sex	5,000	0/10

LD50	> 5,000 mg/kg bw
Signs of Toxicity	There were no deaths. No signs of systemic toxicity were noted.
Effects in Organs	No abnormalities were noted at necroscopy.
Remarks - Results	Body weight gains were as expected. All animals exhibited black coloured faeces on day 1.

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

TEST FACILITY Product Safety Laboratories (2002a)

### B.2. Irritation – skin

TEST SUBSTANCE	Notified polymer (> 90%)
METHOD	US EPA Health Effects Test Guidelines OPPTS 870.2500 Acute Dermal Irritation, August 1998.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 (2 Male 1 female)
Vehicle	Water
Observation Period	7 Days
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP compliant No significant protocol deviations

#### RESULTS

<i>Lesion</i>	<i>Mean Score* 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			
Erythema/Eschar	1	0.7	0	1	< 7 Days	0
Oedema	0.7	0.3	0	1	< 72 Hours	0

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

Remarks - Results	A single 4-hour, semi-occluded application of the test material to the intact skin of the three rabbits produced very slight erythema in three animals and very slight oedema in two animals. One treated skin site appeared normal at the 24-hour observation, one at the 72 hour observation and the remaining treated skin site appeared normal at the 7-day observation.
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No corrosive effects were noted.

CONCLUSION The notified polymer is slightly irritating to the skin.

TEST FACILITY Product Safety Laboratories (2002b)

### B.3. Irritation – eye

TEST SUBSTANCE Notified Polymer (> 90%)

METHOD US EPA Health Effects Test Guidelines OPPTS 870.2400 Acute Eye Irritation, August 1998.

Species/Strain Rabbit/New Zealand White

Number of Animals 3 Female

Observation Period 72 Hours

Remarks - Method GLP compliant

No significant protocol deviations

### RESULTS

<i>Lesion</i>	<i>Mean Score*</i> <i>Animal No.</i>			<i>Maximum</i> <i>Value</i>	<i>Maximum Duration</i> <i>of Any Effect</i>	<i>Maximum Value at End</i> <i>of Observation Period</i>
	1	2	3			
<i>Conjunctiva: redness</i>	0	0	0.3	2	< 48 hours	0
<i>Conjunctiva: chemosis</i>	0	0	0	2	< 24 hours	0
<i>Conjunctiva: discharge</i>	0	0	0	2	< 24 hours	0
<i>Corneal opacity</i>	0	0	0	0	0	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 A single application of the test material to the non-irrigated eye of three rabbits produced conjunctival irritation. Two treated eyes appeared normal at the 24 hour observation with the remaining eye appearing normal at the 48 hour observation.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY Product Safety Laboratories (2002c)

**APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS****C.1. Environmental Fate****C.1.1. Biodegradability**

TEST SUBSTANCE	Humic substances
METHOD	Literature method
Inoculum	Unspecified soil microbes
Exposure Period	1 year
Auxiliary Solvent	None
Analytical Monitoring	Total C and N was determined with a Perkin Elmer 2400 CHN Analyser, and radioactivity was measured with a Beckmann LS60001C liquid scintillation counter.
Remarks - Method	Uniformly $^{14}\text{C}$ labelled <i>Populus fremontii</i> leaf litter that had decomposed for 180 days was fractionated to give humic acid and other fractions. These fractions were added to intact cores of soil or sand inoculated with soil microbes. Respired $^{14}\text{CO}_2$ was collected in NaOH and the radioactivity was counted. The substrate carbon mineralised after 1 year was determined.
RESULTS	
Remarks - Results	<p>After 1 year the substrate carbon mineralised in soil for the humic acid fraction was 12.7%, and was estimated to have a half life of 10 years. Approximately 10% less carbon was mineralised in the sand samples for the humic acid fraction and, therefore, the slow rate of mineralisation of humic acid in soil is not due to adsorption to soil mineral components. These results indicate that humic substances are inherently difficult for microbes to metabolise.</p> <p>An increase in the percentage of humic acid over the period of the study suggest that humic acid has a tendency to accumulate in soil.</p>
CONCLUSION	The notified polymer has a half life of 10 years.
TEST FACILITY	Qualls (2004)

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