File No: STD/1491, STD/1492, STD1494

July 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Schinopsis lorentzii, ext., bisulfited (STD/1491)
Tannins, sodium salts (STD/1492)
Tannins, ammonium salts (STD/1494)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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

This Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1491 STD/1492 STD/1494	All Raw Materials Pty Ltd	Schinopsis lorentzii, ext., bisulfited (STD/1491) Tannins, sodium salts (STD/1492) Tannins, ammonium salts (STD/1494)	ND*	≤ 350 tonnes per annum	Leather tanning, water treatment, mining, adhesive manufacture, wood board manufacture and cardboard manufacture.

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymers are not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 2	H401 - Toxic to aquatic life
Chronic Category 2	H 411 - Toxic to aquatic life with long lasting effects

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymers are not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified polymers are not expected to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymers as introduced:
  - Avoid skin and eye contact

- In the interest of occupational health and safety, the following precautions should be observed for use of the notified polymer as introduced in powder form:
  - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m^3.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymers are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified polymers should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified polymers should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

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

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymers has changed from leather tanning, water treatment, mining, adhesive manufacture, wood board manufacture and cardboard manufacture, or is likely to change significantly;
  - the amount of polymers being introduced has increased, or is likely to increase, significantly;
  - the polymers have begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymers 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 (M)SDS of the notified polymers provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
All Raw Materials Pty Ltd (ABN: 72 098 703 087)
Eden House, 49 Tatiara Crescent
NARRABEEN NSW 2101

NOTIFICATION CATEGORY
STD/1491: Standard: Biopolymer (more than 1 tonne per year).

STD/1492: Standard (Reduced fee notification): Biopolymer (more than 1 tonne per year) – Chemical is being notified at the same time as a similar chemical.

STD/1494: Standard (Reduced fee notification): Biopolymer (more than 1 tonne per year) – Chemical is being notified at the same time as a similar chemical.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical, toxicological and ecotoxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
STD/1491: REACH (2010)
STD/1492: REACH (2013)
STD/1494: REACH (2013)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
STD/1491: UNITAN ATO, FLOATAN O, D2
STD/1492: Colatan GTH, Colatan GTH liquid, Colatan CF2, Floatan T5
STD/1494: Colatan GT10, Colatan GTF

CAS NUMBER
STD/1491: 100085-70-9
STD/1492: 93686-05-6
STD/1494: 71631-09-9

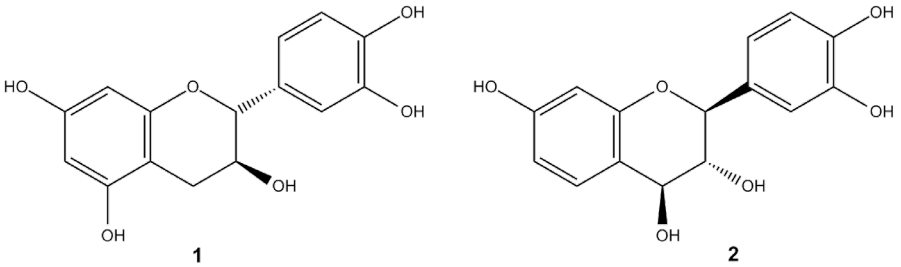
CHEMICAL NAME
STD/1491: Schinopsis lorentzii, ext., bisulfited
STD/1492: Tannins, sodium salts
STD/1494: Tannins, ammonium salts

OTHER NAME(S)
STD/1491: Bisulphited quebracho vegetable extracts
STD/1492: Natural polymer modified *Schinopsis lorentsii*, Quebracho vegetable extracts
STD/1494: Natural polymer modified *Schinopsis lorentsii*, Quebracho vegetable extracts

MOLECULAR FORMULA
Unspecified

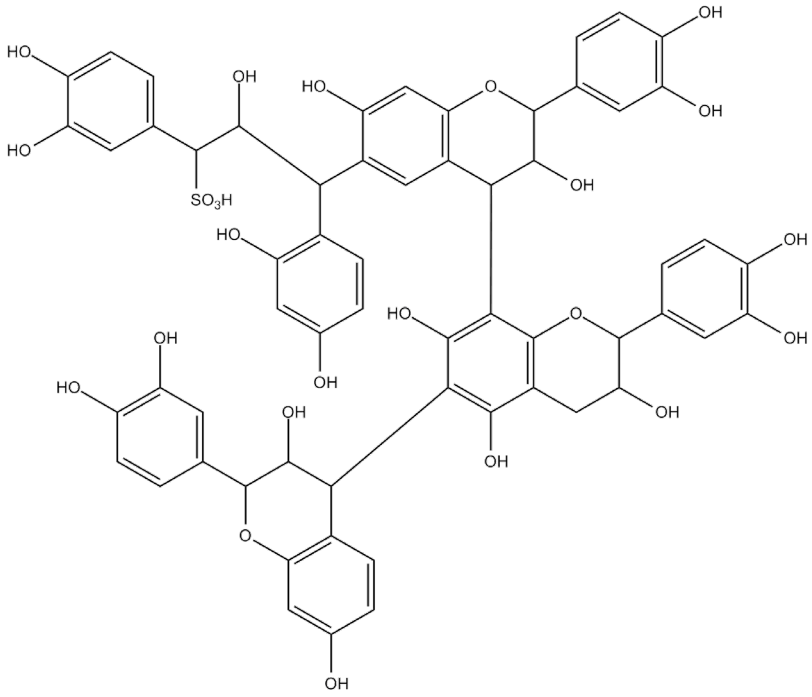
STRUCTURAL FORMULA

The notified polymers are condensed tannins (proanthocyanidins) extracted from heartwood of the quebracho trees (*Schinopsis lorentzii* and *Schinopsis balansae*). Condensed tannins are derived from the oligomerisation of flavan-3-ol units such as catechin, epicatechin and fisetinidol (Quideau et al., 2011). The study authors in the matrix-assisted laser desorption/ionization time of flight mass spectrometry (MALDI TOF MS) study stated that tannins, sodium salts (STD/1492) had a polymeric structure compatible with the presence of fisetinidol and epifisetinidol units linked by covalent bonds (CIT, 2013). Other MALDI TOF MS studies on quebracho extracts revealed that the condensed tannins were oligomers comprised of one catechin unit and one or more *ent*-fisetinidol-4*β*-ol units, otherwise known as profisetinidins (Pasch *et al*., 2001; Venter *et al*., 2012a).



The structures of catechin (**1**) and *ent*-fisetinidol-4*β*-ol (**2**).

Analysis of quebracho extract that was sulfited with sulfurous acid, sodium salt (1:1) has shown that sulfite ions were incorporated at the C2 and C4 positions on the fisetinidol units, with the C2 attack causing the pyran ring to open (Venter *et al*., 2012b).



A sulfited profisetinidin oligomer comprised of one catechin unit and three *ent*-fisetinidol-4*β*-ol units, where C2 sulfitation has occurred on one of the fisetinidol units.

Extraction of the tannin from the chipped wood is done using hot water (100 – 120 °C) to produce a solution of 10 – 11% solids. This solution is then concentrated to 50% solids using multiple effect evaporators before going through a spray dryer plant to produce an extract with an average solids content of 92% with the remaining 8% water. On a dry basis quebracho extract has been determined to be 95% condensed tannins and 5% water soluble sugars (Venter *et al*., 2012a).

MOLECULAR WEIGHT

The molecular weight of tannins, sodium salts (STD/1492) was determined using MALDI TOF MS and hence a NAMW was not determined. However the results of the MALDI TOF MS suggest that the molecular weight of tannins, sodium salts (STD/1492) is comprised of a number of distinct peaks up to ~ 1400 Da. The study by

Venter *et al*. (2012a) showed that the tannins of quebracho extracts are predominantly comprised of profisetinidins containing one catechin unit and either one fisetinidol unit (33% w/w), two fisetinidol units (37% w/w), three fisetinidol units (21% w/w), four fisetinidol units (8% w/w) or five fisetinidol units (1% w/w), which matches the pattern seen in the MALDI TOF MS provided by the notifier. Higher molecular weight profisetinidin oligomers have also been detected in other studies although with decreasing abundance as the molecular weight increases (Pasch *et al*., 2001). The proportion of low molecular weight species < 500 Da in the notified polymers is expected to be low based on the observation that unbound catechin and *ent*-fisetinidol-4*β*-ol units are absent from the central heartwood of quebracho trees (Venter *et al*., 2012a).

ANALYTICAL DATA
Reference MALDI TOF MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
STD/1491: 100%
STD/1492: 100%
STD/1494: 100%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

POLYMER CONSTITUENTS
The notified polymers are a combination of quebracho extract reacted with the following components.

STD/1491

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
Sulfurous acid, sodium salt (1:1)	7631-90-5	4.0-4.8	-

STD/1492

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
Sulfurous acid, sodium salt (1:1)	7631-90-5	4.0-4.8	-
Acetic acid, sodium salt (1:1)	127-09-3	3.0-4.0	-

STD/1494

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*
Sulfurous acid, sodium salt (1:1)	7631-90-5	4.0-4.8	-
Urea	57-13-6	3.0-4.0	-

4. PHYSICAL AND CHEMICAL PROPERTIES

The following physicochemical properties refer to all the notified polymers.

APPEARANCE AT 20 °C AND 101.3 kPa: Brown powder

Property	**Value**	**Data Source/Justification**
Melting Point/Freezing Point	Not determined	Decomposes at 170 °C.
Boiling Point	Not determined	Decomposes at 170 °C.
Density	600 kg/m^3	Not specified - provided by notifier
Vapour Pressure	Not determined	Expected to be low due to the moderately high molecular weight.

Water Solubility	≥ 1000 g/L at 20ºC	Analogue data (STD/1225)
Hydrolysis as a Function of pH	Not determined	The notified biopolymer does not contain any functional groups susceptible to hydrolysis.
Partition Coefficient (n-octanol/water)	log P_{ow} = -3.28 to -3.19	Measured for analogue (STD/1225)
Adsorption/Desorption	log K_{oc} -2.42 to -2.35	Estimated (STD/1225)
Dissociation Constant	pKa = < 0†; 6.96*	†Sulphonic acid group; *Analogue data for phenolic groups for the notified polymer in STD/1225
Particle Size	Respirable fraction (< 10 μm): 80%	Measured
Flash Point	≥ 199 °C	Estimated based on value for tannin[1] (Sax, 1984)
Autoignition Temperature	Not determined	Not expected to autoignite prior to decomposition.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties.

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

Reactivity
The notified polymers are expected to be stable under normal conditions of use.

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymers will not be manufactured within Australia. The notified polymers will be imported as a powder at a concentration of 92% (balance moisture 8%), or at lower concentrations in an aqueous solution.

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

STD/1491

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	300	300	300	300	300

STD/1492

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100	350	350	350	350

STD/1494

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	100	350	350	350	350

PORT OF ENTRY
Fremantle, Adelaide, Melbourne, Sydney and Brisbane

TRANSPORTATION AND PACKAGING
The notified polymers will be imported by sea and air as a powder in 20, 25 and 1,000 kg bags, or as an aqueous solution in 1200 kg plastic containers.

USE

STD/1491: Of the imported notified polymer, 5% will be used in leather tanning, 30% for water treatment and the remaining 65% for mining.

STD/1492: Approximately 5% of the notified polymer will be used in mining, 10% in adhesive manufacture, 15% in wood board manufacture and 70% in cardboard manufacture.

STD/1494: Up to 20% of the notified polymer will be used in mining operations with the remainder used in wood board manufacture.

OPERATION DESCRIPTION

Mining
The notified polymers will be added to the mineral slurry to assist in the extraction of minerals. Any residual material in the mineral slurry from the notified polymers will be processed through water treatment facilities at the mine site.

Wood board, cardboard and adhesive manufacture
The notified polymers will be added to the natural fibre/mineral and reacted to form a phenol-formaldehyde resin. In the manufacture of wood board and cardboard products the notified polymers will act as formaldehyde scavengers to remove any excess formaldehyde.

Leather tanning
Based on the manufacturers recommendations it is expected that when the notified polymer Schinopsis lorentzii, ext., bisulfited (STD/1491) is used in leather tanning it will be dissolved in water with other tanning components at pH levels of 3.5 – 4.8 and temperatures generally < 40 °C. At the end of the tanning process any of the notified polymer that has not become fixed to the leather will be processed at onsite water treatment facilities.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

EXPOSURE DETAILS
It is anticipated that transport and warehouse/stores personnel would only be exposed to the notified polymers in the event of an accident.

Dermal and ocular exposure to the notified polymers at a concentration of 92% will be possible during the transfer of the notified polymers as imported into mixing or storage vessels, during the manufacture of wood board cardboard or adhesives, or in leather tanning or mining, and during cleaning processes. Dermal and ocular exposure to the notified polymers may be limited by the use of personal protective equipment (PPE) including gloves, protective clothing and safety glasses as recommended on the (M)SDS. Inhalation exposure is not expected when the notified polymers are imported in solution as the vapour pressure is expected to be low. However, when the notified polymers are imported as powders inhalation exposure is possible with the respirable fraction (< 10 μm) being 80%. Inhalation exposure may be minimised by the use of local exhaust ventilation and appropriate respiratory protection, both of which are recommended on the (M)SDS of the notified polymers.

Workers will experience dermal exposure to wood board, cardboard and leather products containing the notified polymers. However, the notified polymers will be bound within the products and hence will not be bioavailable.

6.1.2. Public Exposure
The notified polymers are intended for industrial use only, and will not be available to the public. The public may have dermal contact with wood board, cardboard and leather products containing the notified polymers. However, the notified polymers will be bound within the products and hence will not be bioavailable.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on analogues of the notified polymers are summarised in the following table. For full details of the studies, refer to Appendix B and STD/1225.

Endpoint	*Result and Assessment Conclusion*
Rat, acute inhalation toxicity	LC50 > 6.66 mg/L/4 hour; low toxicity[1]
Rabbit, eye irritation	slightly irritating[2]
Mutagenicity – bacterial reverse mutation	non mutagenic[1]

1. Solubilised sulphited quebracho extract (STD/1225)
2. Quebracho extract

Toxicokinetics, metabolism and distribution.

Dermal absorption of the notified polymers is predicted to be low due to the expected high hydrophillicity (analogue water solubility ≥ 1000 g/L at 20ºC and partition coefficient log P_{ow} = -3.28 to -3.19) of the notified polymers making it difficult for them cross the lipid rich environment of the stratum corneum (ECHA, 2012). The moderately high molecular weight (expected to be predominantly > 500 Da.) will also decrease the potential for dermal absorption of the notified polymers (ECHA, 2012).

Acute toxicity.

There were no acute toxicity studies available for the notified polymers.

The notified polymers are expected to be of low acute oral toxicity based on acute oral LD50 values in rats for various tannins which are 1,550 mg/kg bw (Aleppo), 3,700 mg/kg bw (Tara), 2800 mg/kg bw (Chinese), 2,650 mg/kg bw (Sicilian sumac) and 7,500 mg/kg bw (Douglas fir) (US EPA, 2006). Tannic acid (CAS No. 1401-55-4) was also found to be of low toxicity in all reported acute oral studies with LD50 values of 2,260 and 5,000 mg/kg for rats, 5,000 mg/kg for rabbits and 6,000 mg/kg for mice (RTECS, 2014).

A median lethal dose of > 1,600 mg/kg was found for quebracho extract injected subcutaneously into mice (Armstrong et al., 1956). Based on this study and the expected low potential for dermal absorption, the notified polymers are expected to be of low acute toxicity via the dermal route.

The notified polymers are expected to be of low toxicity via the inhalation route in rats based on a study with sulphited quebracho extract (STD/1225).

Irritation and sensitisation.

There were no irritation or sensitisation studies available for the notified polymers.

Quebracho extract, which is the starting material for making the notified polymers was found to be slightly irritating to the eyes of rabbits. The notified polymers may therefore have the potential to be slightly irritating to eyes.

The notified polymers contain phenol groups which have been associated with skin irritation (Hulzebos et al. 2005). However given the relative high molecular weight of the notified polymers, skin irritation potential is expected to be low.

The notified polymers contain catechol groups which have been associated with skin sensitisation (Barratt et al. 1994). The skin sensitisation potential may be diminished by the relative high molecular weight of the notified polymers. There is a report of skin sensitisation in humans following exposure to quebracho extract (Calan & Cronin, 1978); however, this is thought to be the only reported case (van Ketel & Bruynzeel, 1991). Overall, based on the weight of evidence, the skin sensitisation potential of the notified polymers is expected to be low but cannot be totally ruled out.

Repeated dose toxicity.

There were no repeated dose toxicity studies available for the notified polymers.

In a study by Hervás *et al*. (2003) sheep were fed quebracho tannin extract for 21 days at doses of 0, 500, 1,500 or 3,000 mg/kg bw/day. In the control and the two lower dose groups no adverse treatment related effects were noted. In the high dose group feed intake declined until it was practically nil by day 8 and the animals were euthanized on day 10 for humane reasons and were found to have lesions in the digestive tract. Similar lesions were seen in sheep fed pelleted grass meal containing quebracho tannin at 50 g/kg (Dawson *et al*., 1999).

In a study by Gnanamani *et al*. (2008) tannins (including condensed tannins from mimosa and quebracho) were isolated from leather tanning wastewater and administered orally at concentrations of either 500, 1,000 or 1,500 mg/kg bw/day to rats for 12 days. No adverse changes were seen in the rats dosed at 500 mg/kg bw/day, however, at the higher two dose levels significant reductions in triglyceride levels were observed. The same research group showed damage in the liver, kidney and heart tissue of rats orally dosed with 1,500 mg/kg bw/day for 7 days, with lesser effects at 1,000 mg/kg bw/day and no adverse effects at 500 mg/kg bw/day (Sudha *et al*., 2008).

No adverse test substance related changes were noted in rats dosed for 12 weeks at concentration of up to 800 mg/kg bw/day of Aleppo, tara, Chinese, Sicilian sumac and Douglas fir tannins (JECFA, 1970). No adverse treatment related effects were observed in two year studies in both rats and dogs where the animals received up to 0.25% Peruvian tara tannin in their diets (JECFA, 1970).

No adverse test substance related changes were noted in rats and dogs dosed with a hawthorn (*Crataegus* sp) extract (containing 18.75% oligomeric procyanidins) at doses up to 300 mg/kg bw/day intragastrically for 26 weeks (WHO, 2004).

Based on the results of the above studies the notified polymers are expected to be of low chronic toxicity following repeated exposure. This is supported by the fact that condensed tannins are found in a number of food items regularly consumed by humans, such as lentils (up to 1040 mg/100 g) and fruit (up to 160 mg/100 g in grapes) (Santos-Buelga and Scalbert, 2000).

Mutagenicity/Genotoxicity.
There were no mutagenicity or genotoxicity studies available for the notified polymers.

Solubilised sulphited quebracho extract was found to be non-mutagenic in a bacterial reverse mutation assay both in the presence and absence of metabolic activation (STD/1225).

Tannic acid was shown to produce DNA single-strand breaks in an *in vitro* Comet assay with Chinese hamster cells (Labieniec & Gabryelak, 2003). However, in an *in vivo* study in rats tannic acid did not induce DNA single-strand breaks (Oler *et al*., 1976).

Based on the results of the above studies the notified polymers are not expected to be mutagenic or genotoxic.

Toxicity for reproduction.
In a three-generation study in rats fed Peruvian tara tannin at concentrations of 0.058% (29 mg/kg bw/day), 0.117% (60 mg/kg bw/day) and 0.234% (117 mg/kg bw/day), pups in the high dose group had significantly lower weights at weaning (JECFA, 1970; US EPA, 2006).

Mice fed a continuous diet containing 8% tannic acid produced smaller litters with a slower growth rate (Peaslee & Einhellig, 1973). When the mice were only fed the tannic acid diet for 9-11 weeks prior to breeding no adverse developmental effects were noted.

No developmental effects were seen in studies with mice and rats dosed orally with tannic acid at concentrations up to 135 and 180 mg/kg bw/day respectively on days 6-15 of gestation (US EPA, 2006).

Although there were developmental effects seen in some of the studies above the effects were largely limited to lower weight of the offspring at weaning when given high doses of tannins. Due to the absence of reproductive effects or any morphological developmental changes in the studies above it is expected that the notified polymers will be of low developmental and reproductive toxicity.

Health hazard classification
Based on the available information, the notified polymers are not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on toxicological studies on analogues of the notified polymers it is expected that they will be of low toxicity, presenting only as slight skin and eye irritants. However the skin sensitisation potential of the notified polymers, although expected to be low, cannot be totally ruled out.

Workers may have dermal and ocular exposure to the notified polymers as introduced at concentrations of up to 92%. The recommended use of PPE by the notifier should reduce the potential for exposure. Workers will also experience dermal exposure to the notified polymers when handling wood board, cardboard and leather products containing them. However, the notified polymers will be bound within the products and hence will not be bioavailable.

When the notified polymers are imported as powders inhalation exposure is possible with the respirable fraction (< 10 μm) being 80%. If inhaled, due to the low molecular weight and high water solubility of the notified polymers, it is expected that they will be readily cleared from the upper respiratory tract 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 appropriate respiratory protection and local exhaust ventilation by workers when handling the powdered notified polymer should reduce inhalation exposure levels and hence lower the risk of temporary lung overloading. The risk of acute toxic effects following inhalation exposure to the notified polymers is expected to be low based on the low acute inhalation toxicity of an analogous polymer.

Overall, given the expected low toxicity of the notified polymers they are not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

The notified polymers are intended for industrial use only, and will not be available to the public. The public may have dermal contact with wood board, cardboard and leather products containing the notified polymers. However, the notified polymers will be bound within the products and hence will not be bioavailable. Therefore, the notified polymers are not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymers are modified biopolymers and will be imported into Australia as a powder at a concentration of 92%, or at lower concentrations in an aqueous solution. They will be used in applications including leather tanning, mining, water treatment, and manufacture of adhesives, wood board and cardboard in Australia. No further reformulation is expected to occur in Australia. Releases of notified polymers from transportation and storage via accidental spills are not expected to be significant and are expected to be collected for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

Mining

The notified polymers will be added to the mineral slurry to assist in the extraction the desired components. Most of the notified polymers are expected to react with multi-valent metal ions and become insoluble in water (Slabbert N, 1992). Any residual material in the mineral slurry from the notified polymers will be processed through water treatment facilities at the mine site. The notified polymers are negatively charged and are expected to bind to cations in clay, sediment or slurry after use.

Water treatment

In the case of water treatment, the notified polymers are added to boiler systems to prevent rust by reaction with free iron. During use, the notified polymers are expected to react with the metal ions and form insoluble

complexes in water (Slabbert, 1992). The insoluble products may deposit on the wall of the boiler system and be removed periodically for disposal to landfill.

Wood board, cardboard and adhesive manufacture

The notified polymers will be added to the natural fibre/minerals and reacted to form a phenol-formaldehyde resin. In the manufacture of wood board and cardboard products the notified polymers will act as formaldehyde scavengers to remove any excess formaldehyde. Most of the notified polymers are expected to be consumed through the reaction and become part of the phenol-formaldehyde resin which is not soluble in water.

Leather tanning

At the end of the tanning process any of the waste notified polymers will be processed at onsite water treatment facilities. The treatment processes of tanning waste can include primary treatment, physical-chemical treatment, biological treatment and advanced treatment. Through these processes, particles, settleable organic or inorganic solids and biodegradable dissolved matter are expected to be removed.

The notified polymers are expected to associate with sludge sediment and to be removed due to the presence of the negative charges (Darley, 1988). The polymers may also precipitate via chelating with metal ions. They are also expected to be biodegradable although not readily biodegradable. Therefore, most of the waste notified polymers are expected to be removed in the treatment processes through sedimentation and biodegradation processes.

Conclusion on releases

In conclusion, most of the notified polymers are expected to be consumed during the applications. The unused notified polymers are expected to readily react with multi-valent metal ions from waste water or slurry (mining use), forming insoluble products, which can be removed from water. The polymers may also be removed from water through association to sediment in water treatment processes. Biodegradation in the water treatment processes can also contribute to removal of the notified polymers from water. Therefore, no significant release of the notified polymers to the environment surface water is expected from the proposed uses.

RELEASE OF CHEMICAL FROM DISPOSAL

Any accidental spillage is expected to be collected for disposal to landfill. The residues from equipment cleaning are expected to be disposed of to landfill or processed through onsite water treatment plants for mining applications. Empty containers are expected to be disposed of to landfill. The notified polymers that are used in leather tanning or manufacture of wood board, cardboard and adhesive manufacture are expected to share the fate of the associated articles. The most likely case is to be sent to landfill at the end of the articles' useful life.

7.1.2. Environmental Fate

The notified polymers are expected to be biodegradable but not readily biodegradable in seawater. For the details of the environmental fate studies please refer to Appendix C. They may be more biodegradable in fresh water. The notified polymers are not expected to bioaccumulate given they are water soluble.

Most of the notified polymers may be consumed during applications, and to be sent to landfill with the associated articles at the end of their useful life. Some of the notified polymers may be released to waste water treatment plants for further treatment before release to public surface waters. In the treatment plants, most of the notified polymers are expected to be removed via adsorption to sludge, sedimentation after reaction with multi-valent metal ions, and biodegradation. The notified polymers associated with sludge are expected to be finally sent to landfill. A small amount of notified polymers may be directly disposed of to landfill as wastes from spills, residues, and equipment cleaning. In landfill, the notified polymers are expected to undergo biotic or abiotic degradation, forming water and oxides of carbon, and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation of predicted environmental concentration (PEC) has not been conducted since no significant release is expected based on the proposed use pattern and the structural information of the notified polymers. Particularly, the notified polymers released in to onsite waste water treatment plants are expected to be removed from water via adsorption/binding to cations in clay, sediment or slurry.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on acceptable analogue polymers (notified polymer in STD/1225 and the raw material) are summarised in the table below. Details of these studies can be found in Appendix C and STD/1225.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h EC50 ≥ 1800 mg/L	Not harmful*
Copepod Toxicity	48 h EC50 =73.2 mg/L	Harmful
Invertebrate Toxicity	21 d NOEC = 10 mg/L	Not harmful**
Algal Toxicity	72 h E_rC50 = 2.15 mg/L	Toxic***
Lemna Toxcity	7 d EC50 ≥ 1000 mg/L	Not harmful
Amphipods	10 d EC50 ≥ 12,821 mg/kg	Not harmful

* Treat with caution as the actual concentration of the test substance in the test solutions may have been much lower than the nominal amount.

** For the raw material.

**** The observed effects may be from light shielding from the colour of the test substance.

The notified polymers are considered to be toxic to aquatic organisms based on the endpoint of the analogue polymer for alga. It is also noted that this high toxicity may be from the light shielding effects from the colour of the notified polymers. The classification under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) has been made based on this endpoint for alga for a conservative consideration. The notified polymers are formally classified as 'Acute Category 2; Toxic to aquatic life' under the GHS. Based on the acute toxicity data and the lack of ready biodegradability in seawater, the notified polymer is formally classified as 'Chronic Category 2; Toxic to aquatic life with long lasting effects' under the GHS.

7.2.1. Predicted No-Effect Concentration

The PNEC was not calculated since the PEC was not calculated.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) was not calculated since the PEC was not available. The notified polymers released into water streams are expected to be removed by adsorption to sediment or sludge. Therefore, no significant release of the notified polymers to the public environment is expected from the proposed use pattern.

Based on the assessed use pattern the notified polymers are not considered to pose unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Particle Size

Method Optic microscopy with a portion grid

Range (μm)	*(%)*
< 1	30
1 – 5	30
5 – 10	20
> 10	20

Remarks The test states that the analysis was conducted on a 'spray dried quebracho extract'.
Test Facility CIT (2010)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Irritation – eye

TEST SUBSTANCE: Quebracho extract

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	8 Days
Remarks - Method	No significant protocol deviations

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	0.7	1	2	< 7 days	0
Conjunctiva: chemosis	2	0	0.7	4	< 7 days	0
Conjunctiva: discharge	†	†	†	3	< 4 days	0
Corneal opacity	0.3	0	0.3	1	< 8 days	0
Iridial inflammation	0	0	0	0	-	0

* Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.
† Discharge values were not provided apart for the 1 hour observation, although the test report mentions that discharge was seen at up to 4 days after administration.

Remarks - Results: A single application of 0.1 g of the test material to the non-irrigated eye of three rabbits produced slight to severe conjunctival irritation in all animals and slight corneal opacity in two of three animals. All treated eyes appeared normal by the 8 day observation. There were no effects from the test substance on the iris. There were no signs of systemic toxicity and bodyweight gains were with the normal range.

CONCLUSION: The test substance is slightly irritating to the eye.

TEST FACILITY: BSL (2010)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Quebracho extract (raw material)
METHOD	OECD TG 211 *Daphnia magna,* Reproduction Test (1998)
Species	*Daphnia magna*
Exposure Period	21 d
Auxiliary Solvent	None
Water Hardness	36 - 87 mg Ca/L
Analytical Monitoring	Total phenol concentration was used as a surrogate measure of test item concentration. Total phenol concentration was determined using the Prussian Blue Assay, with the modification that the reagent ferric ammonium sulphate was used as a substitute for ferric chloride. Gallic acid was used as the analytical method reference material and the analytical results are reported as gallic acid equivalents.
Remarks - Method	The test was conducted following the above test guideline and good laboratory practice (GLP). Daphnids were exposed to an aqueous solution of the test substance at nominal concentrations of up to 160 mg/L. The EC50, together with 95% confidence limits, was determined for immobilisation and reproduction using Maximum Likelihood Regression. The no observed effect concentration (NOEC) was determined using Williams Multiple Sequential t-test for the reproduction endpoint and Fisher's Exact Binomial Test with Bonferroni Correction for the immobilisation endpoint. All analyses were performed using the statistical computer programme ToxRatPro Version 2.10 (ToxRat. Alsdorf. Germany).

Nominal concentration/time-weighted mean gallic acid equivalent concentration, average number of offspring released and standard deviations and survival of parental daphnids.

	Nominal/Time-weighted Mean Gallic Acid Equivalent Concentration (mg/L)							
Test Day 21	*Control*	*1/n.d.*	*5/n.d.*	*10/n.d.*	*20/2.8*	*40/6.2*	*80/10.7*	*160/27*
Mean number of mobile offspring released (± standard deviation) per survivor	172.4 (±29.0)	183.7 (±22.6)	168.4 (±24.6)	162.5 (±27.8)	147.5 (±27.6)	0	0	0
No. of adult *Daphnids* Immobilised	0	1	2	0	2	10	10	10
% Survival	100	90	80	100	80	0	0	0

21 day EC50 (Immobilisation)	23.6 mg/L
21 day EC50 (Reproduction)	> 20 mg/L
21 day NOEC	10 mg/L (reproduction)
Remarks - Results	The test validity criteria wet met. In order to calculate the time-weighted mean gallic acid equivalent concentration for this test item concentration, the sample which fell below the limit of quantitation was assigned a gallic acid equivalent concentration of 1 mg/L, which was the limit of quantitation for the analytical method. The endpoints were expressed based on the nominal concentrations. The NOEC of the test item to the reproductive output of *D. magna* was10 mg/L. The NOEC of the test item to the immobilisation output of *D. magna* was 20mg/L. The test substance is considered as an acceptable analogue for the

	notified polymers.
CONCLUSION	The test substance and, by inference, the notified polymers are not harmful to daphnids on a chronic basis
TEST FACILITY	Ecotox (2010)

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