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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Succinoglycan (Rheozan)

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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:	www.nicnas.gov.au

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TABLE OF CONTENTS

Succinoglycan (Rheozan)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Rhodia Australia Pty Ltd
352 Ferntree Gully Road, Clayton, VIC 3168
ABN: 24 050 029 000

NOTIFICATION CATEGORY
Standard: Biopolymer with NAMW ≥ 1000 (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Other names
- Molecular formula
- Structural formula
- Spectral Data
- Degree of Purity
- Molecular weight details
- Polymer Constituents
- Residual Monomers and impurities
- Import Volume
- Site of reformulation

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

- Physicochemical Properties
- Acute Dermal Toxicity
- Acute Inhalation Toxicity
- Skin Sensitisation
- Repeat Dose Toxicity
- Genotoxicity (in vitro)

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
Succinoglycan

OTHER NAME
Modified Polysaccharide

CAS NUMBER
73667-50-2

MARKETING NAME
Rheozan

METHODS OF DETECTION AND DETERMINATION

METHOD Infrared spectroscopy and NMR spectroscopy. Gel Permeation Chromatography determined the molecular weight.
Remarks Spectra Provided

3. COMPOSITION

DEGREE OF PURITY
> 80%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

ADDITIVES/ADJUVANTS
None

DEGRADATION PRODUCTS
Fumes produced when heated to decomposition may include carbon monoxide and carbon dioxide.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Any residual starting material and impurities are likely to be incorporated into the finished products with the notified biopolymer.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified biopolymer will not be manufactured in Australia. The notified biopolymer will be imported in 25 Kg lined paper bags in cardboard boxes as a neat powder and will be formulated into finished product at < 1% concentration

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 30	< 30	< 30	< 30	< 30

USE
Thickening agent for aqueous media for various industrial and consumer applications. One of the typical uses is as a thickener in a toilet bowl cleaner.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
The notified biopolymer will be imported through Melbourne by wharf.

IDENTITY OF MANUFACTURER/RECIPIENTS
Formulators of household, industrial and personal care products.

TRANSPORTATION AND PACKAGING
The notified biopolymer will be imported in 25 Kg lined paper bags in cardboard boxes as a neat powder. It will be transported by road from wharf to the notifier's site (Rhodia Australia Pty Limited) and stored. No repackaging operations will be carried out at the notifier's site. Rheozan will then be transported by road unopened to the formulators of household, industrial and personal care products.

5.2. Operation Description

Transport and storage

Rheozan will be imported in 25 Kg lined paper bags in cardboard boxes in powder form. Rheozan will be stored in dry and well-ventilated area at the notifier's site and then on-sold and transported to formulators. After formulation of the finished product, containing the notified biopolymer at < 1% concentration, it will then be sold to retail outlets. One example of the finished product is toilet bowl cleaners.

Formulation – Toilet Bowl Cleaners
At the formulation site the 25 kg bags containing Rheozan are removed from boxes and bags containing the powder and manually transferred to weighing station where it is weighed in a designated dispensary featuring full fume extraction. It is then added to other ingredients into a mill and mixed to produce the toilet bowl cleaner. The mixing equipment has 1,000 L capacity. The notified biopolymer is blended with other ingredients in a batch-wise process. Before final packaging of the finished product, Quality Control technicians will be involved in quality control checks on the finished product. The samples are taken via a sampling port into sampling jars. Once the batch has received QA approval it will be pumped via an automatic filling line to a multi-head filling machine where the finished product will be transferred to 500 ml capacity polyethylene bottles fitted with a polyethylene cap. The final concentration of the Rheozan in the product will be < 1%.

Filling and Packaging
The filling line workers operate and clean the automated guarded filling equipment. The packaging operators will pack the final product containers (500 ml plastic moulded bottles) in cartons ready for distribution to retail market outlets.

End-use
The 500 ml plastic bottle containing the finished product will be packed in cardboard cartons and will be distributed by road to retail outlets for sale to consumers. Other formulated finished products may be packed in a variety of consumer containers.

There is potential for some of the formulated finished products (containing < 1% notified biopolymer) to be used occupationally, for example by professional cleaners using cleaning products or beauticians using cosmetic products.

Cleaning products are generally applied with a cloth or sponge, by mop or brush or by spray followed by wiping. In some cases, the cleaning product will be diluted with water prior to application. The dilution factor, which is often on the label, depends on the type of surface to be cleaned, the soil loading, and the type and method of application.

Depending on the nature of the cosmetic product these could be applied a number of ways such as by hand, using an applicator or sprayed.

5.3. Occupational Exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transporting and warehousing	5-10	2-3 hours/day	25 days/year
Operators	4	8 hours/day	50 days/year
Laboratory technicians	1	2-3 hours/day	50 days/year
Packaging operators	4	2-3 hours/day	50 days/year
Maintenance	1	2-3 hours/day	10 days/year

Exposure Details
Importation, Transport and Storage
Exposure to workers involved in the importation, storage and transport of the notified biopolymer is not expected. Exposure may occur in the unlikely event of an accidental spill. Gloves, cover-alls and goggles are available if required.

Formulation of toilet bowl cleaner
Dermal, inhalation and limited ocular exposure to neat notified biopolymer may occur when opening bags and when weighing and adding the notified biopolymer manually into mixing vessel, and

connecting and disconnecting transfer and filling lines. The mixing vessels are enclosed and the filling machines are automated and fitted with local exhaust ventilation to capture any fugitive dust at the source, and hence minimal exposure during these processes is expected, however, dermal exposure may occur due to drips and spills and if containers are overfilled at the filling station. Workers involved in the above activities wear personal protective equipment such as, overalls, safety glasses, safety shoes, gloves, hair covering and facemasks.

Quality Control/Maintenance
Limited dermal and ocular exposure to small quantities of the notified biopolymer (concentration < 1%) may occur during sampling and testing, or during machine maintenance. The laboratory will contain fume hoods and staff will wear safety glasses, laboratory coats and disposable gloves.

End-users
Retail workers (e.g. supermarkets) will unpack the boxes and place the finished formulated products, e.g. toilet bowl cleaners in 500 ml plastic bottles, containing the notified biopolymer at < 1% concentration on supermarket shelves. Exposure is only likely to occur in the event of a spill from damaged containers

Exposure to no more than 1% notified biopolymer could occur during final application of the cleaning/cosmetic products. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible and inhalation of aerosols could occur where application is by spray. The level of exposure will vary depending on the method of application and work practices employed to minimise splashes and spills.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified biopolymer will not be manufactured or repackaged in Australia. Local operation will include transport and storage, formulation and packaging of end products for end use by the general public.

Rheozan in powder form will be imported into Australia in 25 kg lined paper bags and will be transported directly to the notifier's warehouse for housing before being distributed to household, industrial and personal care products formulators.

Release to the environment may occur at the notifier's warehouse in the unlikely event of an accident during transport or if the packaging is damaged.

It is estimated that 1% of the residual polymer would remain in the 25 kg lined paper bags and in mixing equipment after use. Based on 30 tonnes maximum annual importation of the notified biopolymer, it is estimated that 300 kg of the notified biopolymer would remain in the empty bags. The bags along with the residues are sent off site for disposal to landfill. Washings from cleaning of mixing vessels and transfer lines are collected and sent to landfill by waste contractors.

RELEASE OF CHEMICAL FROM USE
The notified biopolymer will be used in household products such as toilet bowl cleaners and other consumer products. It is likely that due the chemical's high viscosity that residue will be left in containers and disposed with domestic garbage. It is estimated that 5% would be left in empty containers (1,500 kg notified biopolymer/year). The garbage will be placed into landfill.

The remaining 28.2 tonnes of the notified biopolymer will be released to the sewer system, as a consequence of use.

5.5. Disposal
The residue in the packaging will be disposed to landfill.

5.6. Public Exposure

Since the notified biopolymer will be in products sold to the general public, widespread public exposure to the notified biopolymer at a concentration of < 1% is expected. The frequency of and route of exposure (dermal, ocular and inhalation) will vary depending on the end use product and the method of application.

An example exposure scenario for use in toilet cleaners is as follows:
The toilet cleaner is packaged in 500 ml polyethylene bottles and is to be used undiluted by squeezing the liquid from the bottle onto toilet bowl. Application of the product is likely to occur twice per week. The method of application minimises the potential for exposure, however, exposure may occur primarily via the dermal route, with chances of accidental ocular exposure.

Since products containing the notified biopolymer are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

The public is unlikely to be exposed to the notified biopolymer during transport, storage, and manufacture except in the accident of an accidental spillage.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20ºC and 101.3 kPa Cream coloured with glints of grey solid fine powder.

Melting Point Not determined.
Remarks Decomposition is expected at high temperatures, > 100ºC. Information was cited in the MSDS, as laboratory reports are not available.

Density 750 – 850 kg/m^3
Remarks Information was cited in the MSDS. Laboratory reports are not available.

Vapour Pressure Not determined.
Remarks Based on its high molecular weight and polysaccharide nature, the notified biopolymer is expected to have low vapour pressure. Laboratory reports are not available.

Viscosity 3250-3700 mPa.s
METHOD 422 AN2120 - Measurement of Brookfield viscosity of 0.3% Rheozan in 1% aqueous hydrochloric acid solution, after 24 hours at 40°C.
Remarks Laboratory reports not available. Information cited in Rhodia Product data sheet.

Water Solubility Soluble. Depending on the concentration, a colloidal solution, thick paste or gel is formed
Remarks Information was cited in a Rhodia product data sheet. Laboratory reports are not available.

Hydrolysis as a Function of pH Not determined.

Remarks Polysaccharides such as the notified biopolymer are susceptible to hydrolysis under extremes of pH. However, in the pH range of 2-12, significant hydrolysis is unlikely to occur (Rhone-Poulenc data sheet 'Rheozan Industrial Grade Biopolymer).

Partition Coefficient (n-octanol/water) Not determined.
Remarks Laboratory reports are not available. The n-octanol partition coefficient is expected to be low. The notified biopolymer is expected to partition to water due to its anticipated high water solubility and low solubility in octanol.

Adsorption/Desorption Not determined.
Remarks Laboratory reports not available. It is likely to be mobile based on water solubility. However, the notified biopolymer is said to have flocculant properties and can bind to positively charged ions in soil, which may reduce its mobility in soil.

Dissociation Constant Not determined. pH of 0.2% aqueous solution is 7-9. The notified biopolymer contains anionic groups and is likely to display typical acidity.

METHOD 422AN3410 The pH value is measured potentiometrically using glass calomel electrodes.

Remarks Laboratory reports not available. Information cited in Rhodia Product data sheet.

Particle Size Through 60 mesh (250 μm): 100%
Through 80 mesh (180 μm): 95% min

Remarks Laboratory reports not available. Information cited in Rhone-Poulenc data sheet "Rheozan food grade succinoglycan – development project". The exact % of respirable and inhalable particles cannot be established form the data provided but can be considered to be up to 95%.

Flash Point Not determined

Remarks The notified biopolymer is a low volatility solid.

Flammability Not determined

Remarks The notified biopolymer is cited as a non-flammable solid in the MSDS. Laboratory reports are not available.

Autoignition Temperature 140°C

METHOD Not specified

Remarks Information was cited in the MSDS. Laboratory reports are not available

Explosive Properties Not determined.

Remarks Laboratory reports not available. There are no chemical groups that would imply explosive properties; therefore the result has been predicted negative.

Dust Explosivity

Remarks A lower dust explosion limit of 125 g/m^3 was cited in the MSDS.

Reactivity

Remarks Rheozan resists hydrolysis by concentrated mineral acids and organic acids. Rheozan solution is reported to be stable in presence of various salts and is compatible with most anionic and non-ionic surfactants. The viscosity of Rheozan solutions is reported to be stable over a wide range of pH and over long storage times.

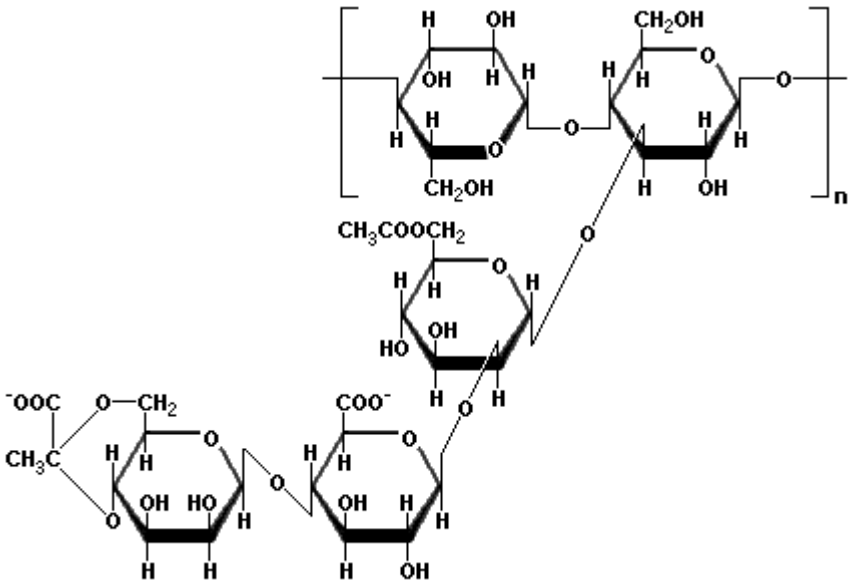
7. TOXICOLOGICAL INVESTIGATIONS

No data is available for the notified biopolymer for the following end-points:

- Acute dermal toxicity
- Acute inhalation toxicity
- Skin sensitisation
- Repeat dose toxicity
- In-vitro Genotoxicity

Xanthan gum, CAS. No. 11138-66-2 http://www.cebitec.uni-bielefeld.de/groups/nwt/microbial_polysaccharides/ is a suitable analogue for the notified biopolymer, having a similar structure and molecular weight.

The repeating unit of Xanthan Gum



Xanthan gum will provide the data gaps noted above (excluding acute dermal toxicity, and in-vitro genotoxicity).

Endpoint and Result	*Test Substance*	*Assessment Conclusion*
Rat, acute oral	Notified biopolymer	Low toxicity, LD50 > 600 mg/kg bw*
Mice, acute oral	Notified biopolymer	Low toxicity, LD50 > 600 mg/kg bw*
Rat, acute dermal	-	Not determined
Rat, acute inhalation	Xanthan gum	Low toxicity, LC50 was not determined in this study
Rabbit, skin irritation	Notified biopolymer	Non-irritating
Rabbit, eye irritation	Notified biopolymer	Slightly irritating
Guinea pig, skin sensitisation	Xanthan gum	No evidence of sensitisation.
Dog, repeat dose (oral diet) toxicity–12 weeks.	Xanthan gum	NOAEL 250 mg/kg bw/day. (additional repeat-dose studies on Xanthan gum are summarised below.)
Genotoxicity –bacterial reverse mutation (Ames test)	Notified biopolymer	Non mutagenic
Genotoxicity – in vitro	-	Not determined
Genotoxicity – in vivo erythrocyte micronucleus test	Notified biopolymer	Non genotoxic
Reproductive effects	Xanthan gum	parental and foetal NOAEL 500 mg/kg bw/day.

Chronic toxicity/Carcinogenicity	Xanthan gum	NOAEL (carcinogenicity) 1000 mg/kg bw/day and NOAEL (other) 370 mg/kg bw/day

* Highest dose tested limited by viscosity.

7.1.1. Acute toxicity – oral

TEST SUBSTANCE	Notified biopolymer
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Rat/Sprague-Dawley
Vehicle	Water
Remarks – Method	Statement of GLP. No significant deviations from standard protocol. The dose 600 mg/kg, corresponded to the maximum dose level it was technically possible to administer. The dose was given over a period of 5 hours in 3 equal fractions, each in a volume of 20 ml/kg.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	600	0
II (Control)	5 per sex	0	0

LD50	> 600 mg/kg bw
Signs of Toxicity	No clinical signs were noted up to 2 hours after the initial administration of the test substance. After 4 hours, hypocinesia was observed in all the animals treated with the test substance. The general behaviour and body weight of the animals were not influenced by the treatment after 24 hours and to day 15.
Effects in Organs	Macroscopic examination of the animals sacrificed at the end of the study revealed no abnormalities.
CONCLUSION	The notified biopolymer is of low toxicity via the oral route up to maximum practicable dose tested.
TEST FACILITY	Rhone-Poulenc (1988a)

7.1.2. Acute toxicity – oral

TEST SUBSTANCE	Notified biopolymer
METHOD	OECD TG 401 Acute Oral Toxicity.
Species/Strain	Mice/Swiss Crl CD-1
Vehicle	Water
Remarks – Method	Statement of GLP. No significant deviations from standard protocol. The dose 600 mg/kg, corresponded to the maximum dose level it was technically possible to administer. The dose was given over a period of 5 hours in 3 equal fractions, each in a volume of 20 ml/kg.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	600	0
Control	5 males and 5 females	-	0

LD50	> 600 mg/kg bw
Signs of Toxicity	General behaviour and body weight of the animals were not influenced by the treatment.
Effects in Organs	Macroscopic examination of animals sacrificed at the end of the study revealed no abnormalities.
Remarks – Results	

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

TEST FACILITY Rhone-Poulenc (1988b)

7.2. Acute toxicity – dermal

Not determined. The biopolymer has a high molecular weight and is unlikely to pass biological membranes. Daily application of a 1% solution of xanthan gum for 15 days to rat skin produced no sign of irritation (JECFA (2006)).

7.3. Acute toxicity – inhalation

TEST SUBSTANCE Xanthan gum - analogue

METHOD

Remarks – Method	Five albino rats received single doses of xanthan gum. The material was administered by inhalation for one hour using a stainless steel inhalation chamber. A total of 19 g of the test material was used during the one-hour exposure, which gave a calculated chamber concentration of approximately 21 mg/liter. Following exposure all rats were observed periodically for one hour for pharmacologic and toxicologic signs over a period of 14 days. Test pre-dates OECD method guidelines

RESULTS

LC50	> 21mg/L/1 hr
Signs of Toxicity	No signs of toxicity were seen and the rats retained good physical appearance throughout.
Effects in Organs	Macroscopic examination of animals sacrificed at the end of the study revealed no abnormalities.
Remarks – Results	Full study report not reviewed. Although classification against the approved criteria is not possible due to the short exposure period, no signs of toxicity or mortality occurred following exposure for a relatively high dose.

CONCLUSION The analogue chemical is of low toxicity via inhalation.

REFERENCE JECFA (2006)

7.4. Irritation – skin

TEST SUBSTANCE Notified biopolymer

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.

Species/Strain	Rabbit/New Zealand White
Number of Animals	6
Vehicle	Water
Observation Period	72 hours
Type of Dressing	Semi-occlusive.
Remarks – Method	Statement of GLP. No significant deviations from standard protocol.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	0	0	0
Oedema	0	0	0	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks – Results: One hour, 24, 48 and 72 hours after the application of the test substance, no cutaneous reaction was observed.

CONCLUSION: The notified biopolymer is non-irritating to skin.

TEST FACILITY: Rhone-Poulenc (1988c)

7.5. Irritation – eye

TEST SUBSTANCE: Notified biopolymer

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain: Rabbit/New Zealand White
Number of Animals: 6
Observation Period: 72 hours
Remarks – Method: Statement of GLP. No significant deviations from standard protocol.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	1	1	24 hours	0
Conjunctiva: chemosis	1.3	2	24 hours	0
Conjunctiva:discharge	1	1	1 hour	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

*Calculated on the basis of the scores at 1 hour for ALL animals.

Remarks – Results: One hour after the introduction of the test substance, moderate conjunctival reactions with a slight discharge were observed in all the animals:

- After 24 hours, only slight conjunctival lesions remained in 4 animals.
- After 48 and 72 hours, the signs of ocular irritation were no longer observed.

CONCLUSION: The notified biopolymer is slightly irritating to the eye.

TEST FACILITY: Rhone-Poulenc (1988d)

7.6. Skin sensitisation

TEST SUBSTANCE: Xanthan gum - analogue

METHOD/RESULTS

Species	*Route of administration*	*Method/Results*
Guinea-pig	Intra-cutaneously	INDUCTION PHASE: Eighteen young adult male guinea-pigs were injected intracutaneously with a 0.1% solution of xanthan gum 3 times per week for a total of 10 injections. CHALLENGE PHASE: Ten days after the last injection, each guinea-pig received a challenge injection. The injection sites were evaluated at 24 hours for size of the erythematous spot and for the intensity of the colour produced. Body weights were recorded at 0, 15, and 30 days. Results: Xanthan gum did not produce sensitization in the guinea-pig under the conditions of the experiment.

Remarks – Method/Results Test pre-dates OECD method guidelines. Full study report not reviewed.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.

REFERENCE JECFA (2006)

7.7. Repeat dose toxicity

TEST SUBSTANCE Xanthan gum - analogue

METHOD/RESULTS

Species	*Route of administration*	*Exposure information*	*Dose Concentrations*	*Results*
Rat	Oral - diet	91-day feeding study	3%, 6%, 7.5%, 15%	At the highest dose diarrhoea did not occur, though abnormally large faecal pellets were produced. A reduced rate of weight gain was found in groups of rats receiving 7.5 or 15% xanthan gum in the diet, while diets containing 3 or 6% gum did not reduce weight gain. A paired-feeding test compared growth for a diet containing 7.5% xanthan gum with comparable rats restricted to the same intake of control diet. No differences in weight gain were found at the end of 18 days, indicating the absence of a growth-inhibiting factor. No significant alterations in haemoglobin, red or white cell counts, or organ weights were observed. Histological examination of tissues at the 15% dose level showed no pathological effects. No No Observed Adverse Effect Level (NOAEL) was stated although from the limited information provided it can be interpreted to be $\geq$ 6% in the diet. This can not be converted to mg/kg bw/day based on information provided.
Rat	Oral – diet	99-110 days	7.5%, 10%	No adverse effects reported. No NOAEL was stated although from the limited information provided it can be interpreted to be 10% in the diet. This can not be converted to mg/kg bw/day based on

				information provided.
Dog/Beagle	Oral diet	14-day feeding study	Four groups of 2 male and 2 female young adults received diets providing 0, 1, or 2 g/kg b.w./day of xanthan gum or 2 g/kg b.w./day of cellulose powder.	Persistent diarrhoea occurred in the high-dose, occasional diarrhoea in the low-dose group. Weight loss was universally observed, including controls, the most marked in animals receiving xanthan gum. Lowered red blood cell counts, haemoglobin concentrations, and serum cholesterol concentrations while relative adrenal weight increased for 2 g/kg b.w./day dose of xanthan gum. These effects were considered to be due to the persistent diarrhoea in this group. Liver and kidney function tests indicated no disturbance. Extensive gross and histopathological examination failed to detect lesions which could be attributed to ingestion of the gum. No NOAEL was stated and could not be established from the information provided.
Dog/Beagle	Oral diet	12 week feeding study	Groups of 3 males and 3 females received diets providing 0, 0.25, or 0.5 g/kg b.w./day xanthan gum.	Animals in the high-dose group had softer stools than normal, but no diarrhoea. Growth was slightly retarded in the males and the serum cholesterol level was lowered in both sexes of the high-dose group. No other adverse effects were seen. The NOAEL in this test was considered to be 250 mg/kg bw/day
Rat/Charles River CD	Oral diet	104 week feeding study	Groups of 30 males and 30 females received diets providing 0, 0.25, 0.5, or 1.0 g/kg b.w./day xanthan gum.	No abnormalities in behaviour, appearance, food consumption, body-weight gain, or survival were found. Ophthalmic and hematologic examination yielded normal results. Blood analysis showed no abnormalities for glucose, aspartate aminotransferase, and prothrombin times. Organ weights were within normal limits, no lesions attributable to xanthan gum were found on gross and histopathological examination. No NOAEL was stated although from the limited information provided it can be interpreted to be 1000 mg/kg bw/day.
Dog/Beagle	Oral diet	107 week feeding study	Groups of 4 males and 4 females received diets providing 0, 0.25, 0.37, or 1.0 g/kg b.w./day Xanthan gum.	No abnormalities in food consumption, body-weight gain, electrocardiograms, blood pressure, heart rate, body temperature, ophthalmic and neurological examinations or survival were found. Stool consistency was normal at the 0.37 g/kg level, but stools were loose at the top-dose level. Faeces weight showed a dose-related increase, to be expected from non-absorbed hydrophilic gum. Haemoglobin, total and differential white cell counts, coagulation and prothrombin times, thrombocyte counts, serum alkaline

		phosphatase, blood urea nitrogen, blood glucose, aspartate aminotransferase, and alanine aminotransferase were the same in control and treated animals. Urine pH, glucose concentration, and sediment content were comparable between test and control groups, but there was a dose-related increase in urine specific gravity consistent with physiological adjustment for extra water excreted in the faeces and a more frequent appearance of urinary albumin in dogs consuming 1.0 g/kg bw/day of gum than in the other groups. Organ weights were within normal limits and histopathological examinations failed to detect any adverse effects at any dose level. No NOAEL was stated although from the limited information provided it can be interpreted to be 370 mg/kg bw/day.

Remarks — Full study report not reviewed. The original reference material all dates pre 1975.

CONCLUSION — The lowest No Observed Adverse Effect Level (NOAEL) for the analogue chemical was established as 250 mg/kg bw/day.

REFERENCE — JECFA (2006)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE — Notified biopolymer

METHOD — In house protocol – plate incorporation method.

Species/Strain — *S. typhimurium*: TA1535, TA1537, TA1538, TA98, TA100.

Metabolic Activation System — Liver fraction (S9 mix) from rats pretreated with Aroclor 1254

Concentration Range in Main Test — a) With metabolic activation: 0 – 1000 µg/plate. b) Without metabolic activation: 0 - 1000 µg/plate.

Vehicle — Water

Remarks – Method — Maximum dose selected based on solubility limit of the test substance observed in the preliminary test.

Deviations from OECD TG 471 Bacterial Reverse Mutation test:

- Strains *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102 not used. These strains can detect certain cross linking mutagens not detected by the other strains.
- 2-Aminoanthracene used as the sole indicator of the efficacy of the S9-mix.

No other significant deviations. Statement of GLP.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present	> 1000			

Test 1		> 1000	not stated	negative (all concentrations)
Test 2		> 1000	not stated	negative (all concentrations)
Absent	> 1000			
Test 1		> 1000	not stated	negative (all concentrations)
Test 2		> 1000	not stated	negative (all concentrations)

Remarks – Results: The test substance did not cause a marked increase in the number of revertants per plate of any of the tester strains either in the presence or absence of activation. Positive controls confirmed the sensitivity of the test system.

CONCLUSION: The notified biopolymer was non-mutagenic to bacteria under the conditions of the test.

TEST FACILITY: Rhone-Poulenc (1990)

7.9. Genotoxicity – in vitro

Not determined. An *in vivo* mouse micronucleus test has been conducted and therefore an *in vitro* chromosome aberration test is not required.

7.10 Genotoxicity – in vivo

TEST SUBSTANCE: Notified biopolymer

METHOD: In house
- Species/Strain: Mice/CD_1/CR
- Route of Administration: Oral – not stated (interpreted to be gavage)
- Vehicle: Not specified
- Remarks – Method: Only a summary of the study was reviewed. The mice (5 per sex per dose) received a single administration or two administrations, 24 hours apart. Doses selected were 592, 888, 1184 mg/jg bw. Due to the solubility limit of the notified biopolymer, each administration was composed of two half-doses approximately two-hours apart.
  The level of micronuclear polychromatic erythrocytes (PCE) in bone marrow was determined 24 hours after a single treatment as well as 48 hours after the first of 2 treatments, 24 hours apart.

RESULTS
- Remarks – Results: Detailed results not reviewed. The test substance at all doses was reported to have no clastogenic effect.

CONCLUSION: The notified biopolymer was not clastogenic under the conditions of this *in vivo* Erythrocyte Micronucleus Test.

TEST FACILITY: Fournier et al (1988)

7.11 Toxicity to reproduction – three generation study

TEST SUBSTANCE: Xanthan gum - analogue

METHOD
- Species/Strain: Rat
- Route of Administration: Oral – diet
- Exposure Information: Exposure period - female: not stated

	Exposure period - male: not stated
Vehicle	diet
Remarks - Method	Criteria evaluated were survival, body weight, general appearance, behaviour, the number of litters produced, number of live births and still births, physical condition of the young, weight at birth and weaning, and survival of the young. Females that had fewer then two litters were examined to determine whether there were foetal resorption. Malformations in offspring were recorded and gross and micropathological examinations were made on the offspring of the second and third generations.

Generation	*Group*	*Number and Sex of Animals*	*Dose/Concentration Mg/kg bw/day*	
			Nominal	*Actual*
P	I	10 male and 20 female	0	not stated
	II	10 male and 20 female	250	not stated
	III	10 male and 20 female	500	not stated
F1	I	10 male and 20 female	0	not stated
	II	10 male and 20 female	250	not stated
	III	10 male and 20 female	500	not stated
F2	I	10 male and 20 female	0	not stated
	II	10 male and 20 female	250	not stated
	III	10 male and 20 female	500	not stated

RESULTS

No adverse effects attributable to the test substance were found in this study.

Remarks – Results

Full study report not reviewed. The original reference material dates pre 1975.

CONCLUSION

The parental and foetal No Observed Adverse Effect Level (NOAEL) for the analogue (notified) chemical was established as 500 mg/kg bw/day.

REFERENCE JECFA (2006)

7.12. Chronic toxicity/carcinogenicity

TEST SUBSTANCE Xanthan gum - analogue

METHOD/RESULTS

Species	*Route of administration*	*Exposure information*	*Dose Concentrations*	*Results*
Rat/Charles River CD	Oral diet	104 week feeding study	Groups of 30 males and 30 females received diets providing 0, 0.25, 0.5, or 1.0 g/kg b.w./day xanthan gum.	No abnormalities in behaviour, appearance, food consumption, body-weight gain, or survival were found. Ophthalmic and hematologic examination yielded normal results. Blood analysis showed no abnormalities for glucose, aspartate aminotransferase, and prothrombin times. Organ weights were within normal limits, no lesions attributable to xanthan gum were found on gross and histopathological examination. No NOAEL was stated although from the

				limited information provided it can be interpreted to be 1000 mg/kg bw/day.
Dog/Beagle	Oral diet	107 week feeding study	Groups of 4 males and 4 females received diets providing 0, 0.25, 0.37, or 1.0 g/kg b.w./day Xanthan gum.	No abnormalities in food consumption, body-weight gain, electrocardiograms, blood pressure, heart rate, body temperature, ophthalmic and neurological examinations or survival were found. Stool consistency was normal at the 0.37 g/kg level, but stools were loose at the top-dose level. Faeces weight showed a dose-related increase, to be expected from non-absorbed hydrophilic gum. Haemoglobin, total and differential white cell counts, coagulation and prothrombin times, thrombocyte counts, serum alkaline phosphatase, blood urea nitrogen, blood glucose, aspartate aminotransferase, and alanine aminotransferase were the same in control and treated animals. Urine pH, glucose concentration, and sediment content were comparable between test and control groups, but there was a dose-related increase in urine specific gravity consistent with physiological adjustment for extra water excreted in the faeces and a more frequent appearance of urinary albumin in dogs consuming 1.0 g/kg b.w./day of gum than in the other groups. Organ weights were within normal limits and histopathological examinations failed to detect any adverse effects at any dose level. No NOAEL was stated although from the limited information provided it can be interpreted to be 370 mg/kg bw/day.

Remarks	Full study report not reviewed. The original reference material all dates pre 1975.
CONCLUSION	The lowest No Observed Adverse Effect Level (NOAEL) for the analogue (notified) chemical was established as 370 mg/kg bw/day. There were no carcinogenic effects were observed at doses up to 1000 mg/kg bw/day.
REFERENCE	JECFA (2006)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE: Notified biopolymer

METHOD: OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test. Commission Directive 92/69/EEC

Inoculum	Activated Sludge
Exposure Period	28 Days
Auxiliary Solvent	Nil
Analytical Monitoring	TOC
Remarks - Method	A preliminary test (OECD guideline No. 209 "Activated Sludge Respiration Inhibition Test") to establish whether the test substance was toxic to the activated sludge was performed. Concentrations of 5, 10 and 20 mg/L were aerated for 3 hours at 21°C in the presence of domestic sewage sludge and synthetic sewage. The results were compared with the blank and a control; 3, 5-dichlorophenol. The test substance was not toxic to activated sludge. Duplicate tests of Rheozan of concentration of 59.3 mg/L ≡ carbon 20 mg/L were inoculated with activated sludge from a STP, which treats predominantly domestic sewage, under aerobic conditions in the dark at 21°C. A blank and reference standard were also run.

RESULTS

Test substance		*Reference Substance (Sodium Benzoate)*	
Day	*% Degradation*	*Day*	*% Degradation*
1	1	1	9
2	3	2	18
3	11	3	32
6	68	6	59
8	81	8	59
10	66	10	70
14	89	14	80
20	98	20	87
22	100	22	87
27	99	27	102
28	99	28	99
29	102	29	101

Remarks - Results: Rheozan showed no inhibition of respiratory rate, in the preliminary toxicity test. Degradation of the test material attained 11% on day 3 and 68% on day 6 of the study, thus satisfying the 10-day window validation criterion given in the OECD Guidelines. The test substance achieved 99% degradation after 28 days. Reference substance showed degradation in acceptable time.

CONCLUSION: The test substance is considered readily biodegradable.

TEST FACILITY: Safepharm Laboratories Limited (1995a)

8.1.2. Bioaccumulation

Not determined. The polymer has high molecular weight, is water-soluble and is readily biodegradable. It is therefore not expected to bioaccumulate.

8.2. Ecotoxicological investigations

8.2.1.1 Acute toxicity to fish

TEST SUBSTANCE	Notified biopolymer
METHOD	OECD TG 203 Fish, Acute Toxicity Test EC Directive 92/69/EEC C.1 Acute Toxicity for Fish
Species	Rainbow Trout (*Oncorrhynhus mykiss*)
Exposure Period	96 Hours
Auxiliary Solvent	Nil
Water Hardness	100 mg $CaCO_3$/L
Analytical Monitoring	Nominal concentrations only, no analysis performed on concentration of test material
Remarks – Method	A range finding test was performed. Three fish were exposed to each of test concentrations of 1.0, 10 and 100 mg/L as well as a control and observed at 24, 48, 72 and 96 hours. After the range finding test duplicate analyses under semi-static conditions were performed on 10 fish per replicate, exposed to a test concentration of 100 mg/L and observed at 3, 6, 24, 48, 72 and 96 hours. A control was also conducted. The conditions were maintained at 14°C with a photoperiod of 16 hours light and 8 hours darkness.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24 h*	*48 h*	*72 h*	*96 h*
Control		3	0	0	0	0
1.0	Not Determined	3	0	0	0	0
10	Not Determined	3	0	0	0	0
100	Not Determined	3	0	0	0	0

Concentration mg/L		*Number of Fish*	*Mortality*					
Nominal	*Actual*		*3h*	*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
Control		10	0	0	0	0	0	0
100	Not Determined	10	0	0	0	0	0	0
100	Not Determined	10	0	0	0	0	0	0

LC50	> 100 mg/L
NOEC	100 mg/L at 96 hours.
Remarks – Results	There were no mortalities nor any behavioural changes observed in the 20 fish exposed to test concentration of 100 mg/L for a period of 96 hours.
CONCLUSION	The notified biopolymer is practically non-toxic to fish.
TEST FACILITY	Safepharm Laboratories Limited (1995b)

8.2.1.2 Acute toxicity to fish

TEST SUBSTANCE	Xanthan Gum analogue
METHOD	Not specified, information extracted from PAN Pesticides Database – Xanthan Gum

Species	*Study*	*End Point*	*Toxic Dose mg/L*
Rainbow Trout	96 hours – static	LC50	320
Rainbow Trout	96 hours – static	LC50	560

Remarks – Results Mean LC50: 420 mg/L

8.2.2. Acute/chronic toxicity to aquatic invertebrates

Not Tested. Due to high molecular weight of the notified biopolymer it is not expected to cross biological membranes.

8.2.3. Algal growth inhibition test

Not Tested. Due to high molecular weight of the notified biopolymer it is not expected to cross biological membranes.

8.2.4. Inhibition of microbial activity

Tested as part of ready biodegradation test (8.1.1). The test substance was not toxic to activated sludge.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified biopolymer is used in household and consumer products such as a thickener for domestic toilet bowl cleaners. During reformulation approximately 1% of the solid product is expected to remain in the import bags. Due to the reformulated product's viscosity it is expected that 5% of the product will remain in the packaging, which will be disposed to landfill as domestic garbage. The product is water-soluble and is readily biodegradable. It is expected to be relatively mobile in landfill but it is likely to be rapidly decomposed by naturally occurring soil bacteria to oxides of carbon and water vapour. It is therefore unlikely to be released to the environment from landfill.

The majority of the chemical will be released to sewer during its intended use.

Chemical released to sewer, (kg).	*Annual sewage outfall across Australia assuming 20.5 million persons and 200L per person per day, (GL)*	*Concentration, (µg/L)*
28,200	1,496	19.22

A worst case predicted environmental concentration (PEC) where no biodegradation of the notified biopolymer occurs is expected to be 19.22 µg/L at the sewage outfall.

9.1.2. Environment – effects assessment

The toxicity results are listed below.

Organism	*Test Substance*	*Duration*	*End Point*	*Toxicity mg/L*
Rainbow Trout	Notified Substance	96 Hours	LC50	≥ 100
Rainbow Trout	Xanthan Gum Analogue	96 Hours	LC50	420

A predicted no effect concentration (PNEC- aquatic ecosystems) of >100 µg/L has been derived by dividing rainbow trout from the notified biopolymer end point of > 100 mg/L by an uncertainty (safety) factor of 1000 (as toxicity data are available only on one species).

9.1.3. Environment – risk characterisation

In a worst-case scenario where no biodegradation occurs the Predicted Environmental concentration (PEC) in rivers and oceans is as follows:

	PEC µg/L	*PNEC µg/L*	*RQ (PEC/PNEC)*
River	19.22	> 100	< 0.19
Ocean	0.192	> 100	< 0.02

From the RQ the release of the chemical to the environment is not expected to pose an unacceptable risk. As the chemical is likely to rapidly biodegrade the risk will be lowered even further.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Household/consumer product formulation and supply

Only transport and storage workers and the formulation operators have the potential for exposure to neat notified biopolymer.

Transport and storage worker exposure to the notified biopolymer is expected to be negligible except in the case of an accidental spill.

Dermal and possibly ocular and inhalation exposure to the notified biopolymer may occur during weighing of the notified biopolymer and during the transfer from the weighing vessel to the blending vessel. The estimated typical case dermal exposure is 3000 mg and 900 mg respectively using measured data for the exposure scenario 'dumping of powders in a formulation facility' (European Commission, 2003). Therefore, for a 70 kg worker and a 10% dermal absorption factor (due to hight molecular weight and expected Kow), reasonable worst-case and typical case dermal exposure is estimated to be 4.3 mg/kg bw/day and 1.3 mg/kg bw/day respectively.

Exposure would be further limited by the presence of local exhaust ventilation and use of personal protective equipment (PPE).

The estimated atmospheric concentration of notified biopolymer due to dust is 5 - 50 mg/m^3, based on EASE model (EASE) using reasonable worst-case defaults (European Commission, 2003). Therefore for a 70 kg worker, assuming an inhalation rate of 1.3 m^3/hour, 8 hour exposure time and 95% inhalable fraction, inhalation exposure is estimated to be 0.7 – 7.0 mg/kg bw/day. Exposure would be further limited by the presence of local exhaust ventilation

Following formulation of the household consumer products, packaging operators, QC staff, transport and storage workers, and supermarket workers have the potential to be exposed to the notified biopolymer (concentration < 1%).

Transport and storage worker, filling packaging operators and supermarket workers are not expected to be exposed to the notified biopolymer except in the event of an accident.

Exposure to the notified biopolymer by QC chemists is expected to be low due to low concentration of the notified biopolymer, the small samples involved and the limited exposure time. Exposure would be limited by the use of PPE.

End use
Workers may be exposed to no more than 1% of the notified biopolymer during final application of the formulated cleaning products or during their addition to water if dilution is required. Although the level of exposure will vary depending on the method of application and work practices employed, exposure is considered to be low due to the low concentration of the notified biopolymer.

9.2.2. Public health – exposure assessment

Use in toilet cleaner
Although public accessibility to the notified biopolymer would be high due to its incorporation into a domestic toilet cleaner, the potential for public exposure is low due to its low concentration (< 1%) in, and the use pattern of, the end product. Application of the product is likely to occur twice a week. Exposure during use of the finished product may occur primarily via the dermal route, with chances of accidental ocular exposure.

Other uses
Since the notified biopolymer will be in products sold to the general public, widespread public exposure to the notified biopolymer at a concentration of 1% is expected. Based on exposure to a range of household, personal care and cosmetic products in Europe (SDA, 2005), public exposure (dermal) to the notified biopolymer through use of a wide range of products containing the notified biopolymer, is estimated to be 0.3 mg/kg bw/day, assuming a bodyweight of 60kg, a 10% dermal absorption factor, a concentration of 1% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. This estimate is considered to be an overestimate as it assumes all products (household, personal care and cosmetic) used by one person contain the notified biopolymer and uses the maximum 'product amount used' from the range in the dataset.

If the notified biopolymer is used in baby care products, a child's exposure is estimated to be 0.3 mg/kg bw/day assuming a bodyweight of 15kg, a 10% dermal absorption factor, a concentration of 1% and that product usage (amount used per use and frequency of use) is similar in Australia to Europe. Since products containing the notified biopolymer are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

9.2.3. Human health – effects assessment

Based upon the toxicological data presented in section 7.1 to 7.10, which includes data on a analogue (xanthan gum), the notified biopolymer has low acute oral and inhalation toxicity, is non-irritating to skin and only slightly irritating to the eye, is not a sensitiser, has a repeat dose NOAEL of 250 mg/kg bw/day, is non-mutagenic and non-genotoxic and is not expected to be carcinogenic or a reproductive toxicant.

It may cause effects to both weight-gain and faeces condition if administered as a dietary supplement. The bio-polymer is a polysaccharide with a β-D-glucose/glucuronic acid/galactose backbone which renders the polymer essentially indigestible in the intestine, except in the presence of bacteria such as those found in the lower gut where partial fermentation may occur.

The biopolymer will be used in products at concentrations less than 1%, considerably lowering the risk of any effect on human health.

Based on the available data, the notified biopolymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Reasonable worst-case exposure to the notified biopolymer during formulation was estimated to be 2-11.3 mg/kg bw/day. Based on a worst-case NOAEL of 250 mg/kg bw/day, derived from a 12-week dog oral study the margin of exposure (MOE) is calculated as 22-125. MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences. Whilst this margin of exposure is lower than the acceptable value, actual exposure is expected to be a lot lower than that estimated due to the conservative nature of the EASE model and the expected low dermal absorption of the notified biopolymer. The presence of engineering controls and use of PPE would further reduce this exposure. As such the risk of adverse systemic effects is considered to be low. As a precaution to minimise any potential risk, work should be carried out under local exhaust ventilation and workers should wear coveralls and impervious gloves and a dust mask when sufficient ventilation is not available. In addition as the notified biopolymer is a slight eye irritant, workers should wear eye protection to reduce the risk of irritation effects.

Following formulation the risks to workers is considered to be low due to the low concentration of the notified biopolymer.

9.2.5. Public health – risk characterisation

Although the notified biopolymer is a slight eye irritant at the low concentration present in the consumer products, the risk of an irritant effect from contact with the notified biopolymer is considered to be low.

Based on a NOAEL of 250 mg/kg bw/day, derived from a 12-week dog oral study the margin of exposure (MOE) from a number of exposure scenarios is calculated as follows:

Product(s) used	*Adult/Child*	*Estimated Exposure <mg/kg bw/day>*	*MOE*
Wide range of household, personal care and cosmetic	Adult	0.3	833

products.			
Baby care products	Child	0.3	833

MOE greater than or equal to 100 are considered acceptable to account for intra- and inter-species differences, therefore, the risk to public health is considered to be low.

Since products formulated with the notified biopolymer will be stored and used in a domestic environment, there is also the possibility for children to be exposed to the notified biopolymer by accidental ingestion. However, as the notified biopolymer is considered to be of low acute toxicity and given the low concentration of the notified biopolymer in the formulated products, the risk of lethal effects as a result of accidental ingestion is considered to be low.

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

10.1. Hazard classification

Based on the available data the notified biopolymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

As a comparison only, the notified biopolymer would not be classified using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003). This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio:
The chemical is considered to pose no 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 Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used as a low-concentration finished product in the manner described

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified biopolymer 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 biopolymer 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
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified biopolymer as introduced:
  - use local exhaust ventilation during weighing and transfer of the notified biopolymer in powder form
  - use a closed system for formulation and mixing

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified biopolymer as introduced:
  - gloves
  - protective clothing
  - eye protection
  - dust mask or respirator when sufficient ventilation is not available.

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified biopolymer 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.

Disposal

- The notified biopolymer should be disposed of by authorised landfill.

Emergency procedures

- Spills or accidental release of the notified biopolymer should be handled by physical collection, whilst avoiding generating dust. Use HEPA vacuum or non non-sparking shovel. Wash residues with water and absorb with an inert absorbent. Transfer to suitable container 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(2) of the Act:
  – if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

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