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17 December 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

α-D-Galactopyranuronic acid, O-6-deoxy-β-L-galactopyranosyl-(1→3)-O-α-D-galactopyranosyl-(1→3)-, homopolymer (9CI)

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Director
Chemicals Notification and Assessment

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Beiersdorf Australia Ltd (ABN 98 000 025 623) of 4 Khartoum Road North Ryde NSW 2113.

NOTIFICATION CATEGORY
Limited-small volume: Biopolymer (1 tonne or less per year).

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

NOTIFICATION IN OTHER COUNTRIES
Japan: CLS no. 532191.

2. IDENTITY OF CHEMICAL

CHEMICAL NAME
α-D-Galactopyranuronic acid, O-6-deoxy-β-L-galactopyranosyl-(1→3)-O-α-D-galactopyranosyl-(1→3)-, homopolymer (9CI)

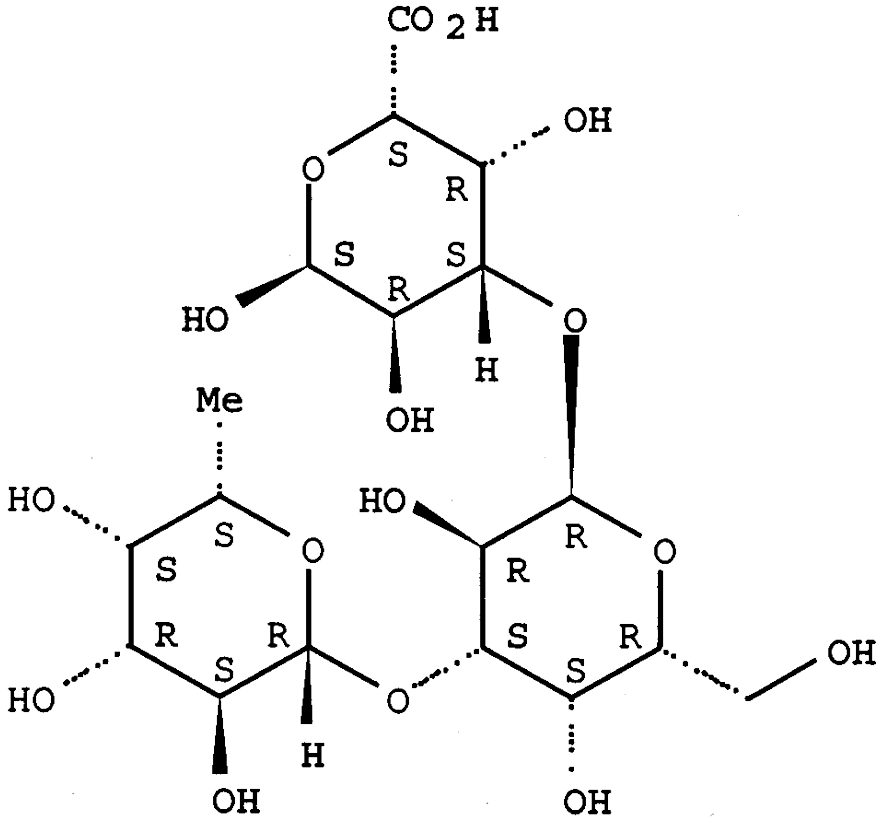
OTHER NAME(S)
Not available.

MARKETING NAME(S)
Biosaccharide Gum-1 (1% notified biopolymer)
Fucogel 1000PP (1% notified biopolymer)

CAS NUMBER
194237-89-3

MOLECULAR FORMULA
$(C_{18}H_{30}O_{16})x$

STRUCTURAL FORMULA
Extracted from SciFinder (2000)



MOLECULAR WEIGHT
1.5×10^6

METHODS OF DETECTION AND DETERMINATION
IR spectroscopy

3. COMPOSITION

DEGREE OF PURITY
>99%

HAZARDOUS IMPURITIES

Chemical Name	Heavy metals (unidentified)		
CAS No.	Not assigned.	*Weight %*	<0.002
Hazardous Properties	Not determined.		

Chemical Name	Arsenic		
CAS No.	7440-38-2	*Weight %*	<0.0002
Hazardous Properties	At Concentrations equal to or more than 25%: Toxic (T): R23/25 - Toxic by inhalation and if swallowed. At Concentrations equal to or more than 3% and less than 25%: Harmful (Xn): R20/22 - Harmful by inhalation and if swallowed.		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

None.

ADDITIVES/ADJUVANTS
None.

POLYMER CONSTITUENTS
The notified biopolymer is a fucose rich polysaccharide produced through biotechnology fermentation of plant material (using GRAS bacteria), and as such monomers were not specifically used in the manufacturing process. The structure of the polymer is based upon L-fucose (CAS no. 219-452-7), D-galactose (CAS no. 200-416-4) and galacturonic acid (CAS no. 211-682-6). No chain transfer chemicals or cross-liking agents are used in the production.

PRODUCT COMPOSITION
The notified biopolymer is not isolated, but produced as 1% aqueous solution under the trade name of Biosaccharide Gum-1 or Fucogel 1000PP. The product is preserved by 0.3% phenonip and 1% phenoxyethanol.

Chemical Name	2-Phenoxyethanol		
CAS No.	122-99-6	*Weight %*	1.0
Hazardous Properties	At Concentrations equal to or more than 25%: Harmful (Xn): R22 - Harmful if swallowed, R36 - Irritating to eyes. At Concentrations equal to or more than 20% and less than 25%: Harmful (Xi): R36 - Irritating to eyes.		
Chemical Name	phenonip		
CAS No.	8066-38-4	*Weight %*	0.3

4. INTRODUCTION AND USE INFORMATION

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

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

Year	*1*	*2*	*3*	*4*	*5*
Kg	5-6	5-6	5-6	5-6	5-6

USE
As a surface enhancing component at ≤ 0.03% in facial creams and moisturisers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Not stated.

IDENTITY OF MANUFACTURER/RECIPIENTS
Beiersdorf Australia Ltd.

TRANSPORTATION AND PACKAGING
The notified biopolymer will be distributed as a 0.01%-0.03% component in a range of fully formulated and packaged Nivea brand face cream and moisturiser products. They are presented in 15 mL and 50 mL individually wrapped containers, then shrink-wrapped into packs of six containers. Two shrink-wrapped packs are fitted into a carton. The products will be warehoused prior to being road transported to retail outlets for sale to the public.

5.2. Operation Description

No reformulation or repackaging will occur in Australia. The Nivea face creams and moisturisers will come into Australia as finished formulations ready for distribution to consumers.

5.3. Occupational exposure

Number and Category of Workers

Not specified.

Exposure Details

The notified polymer is imported in final consumer packages. Therefore, occupational exposure to the notified polymer will be limited to handling of the closed packages during transport, distribution and retail sale. A large number of workers in these sectors will handle the product containing the notified polymer for brief periods, with no exposure expected except in the case of an accident. In addition, due to the style of packaging, it is likely that small quantities would only be spilled if packaging is breached.

Beauticians and beauty salon personnel will likely be in contact with the cream containing the polymer as they apply it to customers' skin. Good handling procedures will help reduce the potential of skin exposure.

5.4. Release

RELEASE OF CHEMICAL AT SITE

No manufacture or reformulation will occur in Australia. The notified polymer will be imported fully formulated in 15 and 50 mL containers at a concentration of 0.01%-0.03%.

RELEASE OF CHEMICAL FROM USE

Since, the notified polymer will be used in facial creams and moisturisers and as such will be washed from the skin, it is expected that up to 98% of the imported volume or 6 kg per annum will be released to the sewer. The remaining 2% or up to 0.1 kg per annum will remain in the import containers and go into domestic rubbish and ultimately to landfill.

5.5. Disposal

The notified biopolymer will ultimately be disposed of in the sewer except a small amount sent to landfill as residues in used containers.

5.6. Public exposure

Public exposure to the notified polymer is possible but unlikely following the rupture of the cosmetic containers as a result of a transport accident.

All of the imported polymer will eventually pass to the environment, either from residues in discarded containers sent to landfill or as a component of used moisturisers entering sewage. In the environment the notified polymer is expected to be highly diluted and immobile in sediment or soil. Public contact with the notified polymer as an environmental contaminant is therefore also unlikely.

The notified polymer is an ingredient in a range of the Nivea brand face creams and moisturisers, therefore, public exposure during end use will be widespread. The main route of exposure will be via dermal contact. It is estimated that approximately 0.8 g product, containing up to 0.03% notified polymer, will be used 1-2 times a day (SCCNFP, 2000).

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Opalescent viscous solution with slight characteristic odour
Freezing Point	<0°C

Remarks Test report not provided.

Boiling Point ~ 100°C

Remarks Test report not provided.

Density 1000 kg/m^3 at 20°C

Remarks Test report not provided.

Vapour Pressure Not determined

Water Solubility Not determined.

Remarks The notified polymer is a polyhydroxylated sugar, a structure which is consistent with high water solubility. In addition, exposure to the basic conditions in the sewer will serve to increase the notified polymer's solubility further (see below).

Hydrolysis as a Function of pH Not determined.

Remarks Polysaccharides such as the notified polymer are susceptible to hydrolysis under extremes of pH. However in the environmental pH range of 4-9, significant hydrolysis is unlikely to occur.

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

Remarks The notified polymer is likely to partition into the aqueous phase due to its expected high water solubility.

Adsorption/Desorption Not determined.

Remarks The notified polymer's expected high water solubility is indicative of a relatively low Koc.

Dissociation Constant Not determined.

Remarks The notified polymer contains alcohol and carboxylic acid groups which are expected to have typical acidity. Exposure to basic condition in the sewer will result in the partial deprotonation of the acid groups which will lead to a further increase in water solubility.

Particle Size Not applicable

Remarks The notified polymer is a liquid.

Flash Point >180°C

Remarks Test report not provided.

Flammability Limits Not flammable.

Remarks Test was not conducted.

Autoignition Temperature Not determined.

Explosive Properties Not determined.

Remarks Not expected to be explosive on structural grounds.

Reactivity Stable under normal conditions.

Remarks	Hazardous polymerisation will not occur. No known reactions or decomposition products.

Viscosity 1000 cps at 30°C

Remarks	Test report not provided.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result (for 1% notified polymer)	*Assessment Conclusion*
Mouse, acute oral LD50 ≥1500 mg/kg bw	low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - non-adjuvant test	no evidence of sensitisation
Human, skin sensitisation	no evidence of sensitisation

7.1. Acute toxicity – oral

TEST SUBSTANCE	Bioeurope No. 856 (Fucogel 1000 – 1% notified biopolymer)
METHOD	Litchfield & Wilcoxon method, as described in Technical Data Sheet No. 6 of the Journal Pharmacologique, 1970, 1, 3, 407-414.
Species/Strain	Mouse/OF1 Albino
Remarks - Method	No recording in procedure standards was provided. The test consisted of a single administration by means of an oesophageal tube and an eight-day observation period. LD50 were calculated using Miller and Tainter's method.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	10 males	200	0
II	10 males	500	0
III	10 males	1000	2
IV	10 males	1500	3

LD50	≥1500 mg/kg bw
Remarks - Results	It was indicated that the number of deaths recorded over the eight days following ingestion was low (5) and similar to those recorded in the untreated control group (3) over the same observation period.
CONCLUSION	The 1% notified biopolymer solution is of low toxicity via the oral route under the conditions of the test.
TEST FACILITY	Biological Chemistry Laboratory, Marseille Uni. (1992)

7.2. Irritation – skin

TEST SUBSTANCE	Bioeurope No. 856 (Fucogel 1000 – 1% notified biopolymer)
METHOD	The method described in the Journal Officiel de la République Française of 22 February 1982 and rediscussed in the issue of 6 January 1983.
Species/Strain	Albino rabbit
Number of Animals	6 (sex not specified)
Observation Period	72 hours
Type of Dressing	Occlusive

Remarks - Method

24 h exposure. No recording in procedure standards was provided. Primary skin irritation was evaluated at 24 h and 72 h after application of 0.5 mL test product to the previously scarified right flanks and to the intact left flanks of six albino rabbits. Scarification was made such that the incisions penetrate the epidermis without reaching the dermis (ie no bleeding occurs due to scarification in any test animals).

RESULTS

Remarks - Results

After 24 h application, slight erythema (score = 1) was observed on the scarified and non-scarified areas of three animals. The other three rabbits did not show any skin lesions (score = 0). Three days after, two rabbits still showed slight redness on the scarified areas. As 1 h and 48 h scores are not available, the Primary Irritation Index cannot be calculated.

CONCLUSION

Due to the poor reporting quality of the study, only an approximate assessment of the skin irritation potential can be made. Based on the available data, the 1% notified biopolymer solution may be slightly irritating to skin.

TEST FACILITY

Biological Chemistry Laboratory, Marseille Uni. (1992)

7.3. Irritation – eye

TEST SUBSTANCE

Bioeurope No. 856 (Fucogel 1000 – 1% notified biopolymer)

METHOD

As described in the Journal Officiel de la République Française of 24 October 1984, 3 May 1990, and 9 June 1992.

Species/Strain: Albino rabbit
Number of Animals: 3 males
Observation Period: 7 days

Remarks - Method

No recording in procedure standards was provided. However, it was claimed this is an official method for evaluating the eye irritation caused by cosmetics and products for personal hygiene.

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	1	0.3	0.3	1	72 h	0
Conjunctiva: chemosis	0.3	0	0	1	24 h	0
Conjunctiva: discharge	0.7	0.3	0.3	1	48 h	0
Corneal opacity	0	0	0	0	0	0
Iridial inflammation	0	0	0	1	1 h	0

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

Remarks - Results

Moderate irritation of the conjunctiva was observed in three rabbits after 1-hour instillation. This consisted of varying degrees of tears, redness of the palpebra, and mild chemosis. One rabbit had slight oedema of the iris. The cornea showed no sign of irritation. All animals had returned to normal by day 4 and this recovery was confirmed after 7-day observation period.

CONCLUSION

The 1% notified biopolymer solution is slightly irritating to the eye under the conditions of the test.

TEST FACILITY

Biological Chemistry Laboratory, Marseille Uni. (1992)

7.4. Skin sensitisation

TEST SUBSTANCE	Fucogel 1000 – Batch 7A486 (1% notified biopolymer)
METHOD	OECD TG 406 Skin Sensitisation – Buehler Test. EC Directive 86/609/EEC - Buehler Test.
Species/Strain	Guinea pig/Hartley, Albino
PRELIMINARY STUDY	Maximum Non-irritating Concentration: topical: 100% (undiluted)
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration: topical: 100% (undiluted)
Signs of Irritation	No cutaneous reactions were observed during the induction phase.
CHALLENGE PHASE	
1st challenge	topical: 100% and 10% (diluted with distilled water).
2nd challenge	topical: 100%
3rd challenge	topical: 100%
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	No clinical signs were noted during the study. In the first challenge, application of Fucogel 1000 undiluted and diluted at 10% to the skin of guinea pigs, either with or without initial exposure to the test substance, did not produce any irritation. Also, no positive response was observed with Fucogel 1000 and benzocaine tested in a second and third challenge performed 14 and 21 days after the first challenge exposure. (Noting that benzocaine is a weak sensitiser.) Two mortalities were observed during the study, however they were not attributable to treatment.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the 1% notified biopolymer solution under the conditions of the test.
TEST FACILITY	Evic-Ceba (1997)

7.5. Skin sensitisation – human

TEST SUBSTANCE	Fucogel 1000PP (1% notified biopolymer)
METHOD	Repeated Insult Patch Test, as outlined in the Federal Register, vol. 46, no. 17, 27 January 1981.
Number of Subjects	47 females, 8 males (52 completed the study), age range 18-77.
Vehicle	Tap water
Type of Dressing	Occlusive
INDUCTION PHASE	Ten repeat, 24-h applications, 3 per week, of 0.2 mL of the test substance to the same skin area of the upper back between the scapulae. Each subject was instructed to keep the patch in place and dry.
REST PERIOD	14 days
CHALLENGE PHASE	Same as the induction phase and applied to the original site with the volar forearm serving as a virgin test site. Challenge sites were examined for dermal reactions 24 and 48 h post application.
Remarks - Method	
RESULTS	Observations remained negative throughout the test period.
Remarks - Results	
CONCLUSION	The 1% notified biopolymer solution did not indicate a potential for dermal irritation and/or sensitisation under the conditions of the test.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted. However, the notifier does make reference to a ready biodegradability test conducted in April 1998 using ISO 10707. The notifier claims that the notified polymer achieved 53% degradation after 7 days and 90% by day 28. As no further details were provided a characterization of the biodegradability potential of the notified polymer cannot be made.

Data regarding the bioaccumulation potential of the notified polymer were not provided. The notifier suggests that a large proportion of the notified polymer will degrade within 28 days, suggesting that the potential for bioaccumulation is low. This will further be reduced by its low import volume, high MW, water solubility and dispersed use pattern.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified polymer will eventually be released into the environment with the majority being discharged into sewerage systems through washing from the skin. It is expected that up to 98% or 6 kg per annum will be released to sewer. The remaining 2% or up to 0.1 kg per annum will remain in the import containers and go into domestic rubbish and ultimately to landfill.

The notified polymer is expected to be highly soluble in water and as such will be mobile in both aquatic and terrestrial compartment. Under the basic conditions generally found in the sewer (pH 8) deprotonation of the acid groups present will occur resulting in anionic character. This will lead to eventual association with soil and sediment where the notified polymer will slowly degrade through biological and abiotic processes to water and oxides of carbon. Residual chemical disposed of into landfill with empty containers are also expected to slowly adsorbed to soil/sediment particles and be slowly destroyed by similar mechanisms to those operating in sediments.

Based on annual imports of 6 kg per annum, and assuming the majority of this is eventually released to the sewer and will not be removed during sewage treatment processes, the daily release on a nationwide basis to receiving waters is estimated to be 1.65×10^{-2} kg/day. Assuming a national population of 19.5 million and that each person contributes an average of 150 L/day to overall sewage flows, the predicted concentration in sewage effluent on a nationwide basis is estimated as 5.6×10^{-6} µg/L.

When released to receiving waters the concentration is generally understood to be reduced by a further factor of at least 10, and so the Predicted Environmental Concentration (PEC) is around 0.56×10^{-6} µg/L. Removal processes such as adsorption to sludge would reduce this value further.

9.1.2. Environment – effects assessment

No ecotoxicological data were submitted. However, the high molecular weight of the polymer would preclude it crossing biological membranes and hence bioaccumulation is considered low. As a result, ecotoxicity would not be expected.

9.1.3. Environment – risk characterisation

Most of the notified polymer will eventually be released into domestic sewage systems as a consequence of product use. With its high water solubility, the polymer is expected to be mobile in both aquatic and terrestrial compartment. However, due to its induced anionic character under the basic conditions of the sewer, the notified polymer is expected to associate with soil and sediment and slowly degraded through biological and abiotic processes to water and oxides of carbon. Further, the compound is inherently biodegradable (90% over 28 days) so its potential for bioaccumulation is low.

No information is available on aquatic toxicity but estimated levels in receiving waters are very low and there is likely to be an adequate safety margin.

Based on limited environmental exposure resulting from its low import volume and dispersed use pattern, the likely risk to the environment is expected to be low.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

As the notified polymer will be introduced as a component of a ready-to-use product in final consumer packages, occupational exposure would be limited to handling of spillages during an accident. The MSDS indicates collection and disposal of the spills will be in accordance with the government regulations.

Beauticians and beauty salon personnel may come in contact with the cream containing the notified polymer when applying it to customers' skin. However, good handling procedures and personal hygiene observation via use of make-up cotton pads will minimise exposure. On the basis that only small amounts of the cream will be handled and the low concentration ($\leq 0.03\%$) of the notified polymer in the cosmetic products, occupational exposure is assessed as low.

9.2.2. Public health – exposure assessment

As the notified polymer is an ingredient of the Nivea brand face creams and moisturisers to be sold throughout Australia, public exposure is expected to be widespread. Dermal and some ocular contact are likely the routes of exposure. However, given the small amounts used per application and the low concentration of the polymer in the products, public exposure to the notified biopolymer is determined to be low.

9.2.3. Human health - effects assessment

The notified biopolymer at 1% is of low acute oral toxicity in mouse (LD50 $\geq$1500 mg/kg bw). It is slightly irritating to the skin and eyes of rabbits when tested at 1%. There was no evidence of sensitisation in guinea pigs (non-adjuvant test) and human subjects exposed to the same concentration of the notified polymer.

With a high molecular weight, dermal absorption of the polymer is anticipated to be low. Therefore, the notified polymer would not pose a significant health hazard when used in the proposed manner.

9.2.4. Occupational health and safety – risk characterisation

On the basis of the low exposure of workers to the polymer, the risk to occupational health and safety is considered negligible.

9.2.5. Public health – risk characterisation

Given the notified polymer will only be used as a $\leq 0.03\%$ ingredient in cosmetic products and its high molecular weight will preclude systemic absorption, the risk to public health is determined 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 polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

On the basis of the low imported volumes and the nationwide and diffuse use, the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is 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 in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the 1% notified biopolymer solution provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). 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 Nivea brand cosmetic products containing ≤ 0.03% notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified biopolymer should be disposed of in landfill.

Emergency procedures

- Spills/release of the notified biopolymer should be handled in accord with the MSDS and government regulations.

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.

13. BIBLIOGRAPHY

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