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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

BioEcolia

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

BioEcolia

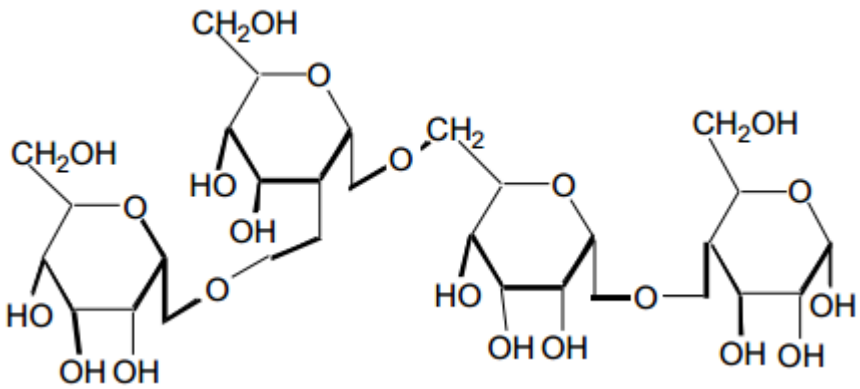
1. APPLICANT

Fernz Speciality Chemicals of 70 Marple Avenue VILLAWOOD NSW 2163 has submitted a limited notification statement in support of their application for an assessment certificate for BioEcolia.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	alpha-glucan oligosaccharide
Chemical Abstracts Service (CAS) Registry No.:	9074-78-6
Other Names:	none
Trade Name:	BioEcolia
Product Name:	Artistry Absolute Oil Control Foundation SPF15 (contains 5% notified chemical)
Molecular Formulae:	unspecified (see notes below)
Molecular Weight:	500 – 1 000

Structural Formula:



Method of Detection and Determination:	The notified chemical is characterised by C18 high pressure liquid chromatography (HPLC)-RI (refractive index) and identified by infrared (IR) spectroscopy
Spectral Data:	major IR peaks were observed at: 1 018.2, 1 150, 1 360, 1 645, 1460.5, 2 923.6 and 3 446.7 cm^{-1}

Comments on Chemical Identity

The new chemical is a selective substrate for bacteria on the skin. A glucosyltransferase enzyme naturally present on the skin hydrolyses BioEcolia to produce a bioselective substrate that facilitates the growth of desired cutaneous flora. The notified substance is a white powder with a sweet odour and can be detected using a C18 column on a HPLC machine and later identified using IR spectroscopy. Data from IR spectroscopy has been provided for the chemical and identifies the major functionalities.

The notifier did not provide a molecular formula because the new chemical is made up of polymerised oligosaccharides, namely combinations of sucrose and maltose units which are hydrolysed on the skin by a glucosytransferase, to glucose and fructose. The molecular weight for the notified chemical ranges from 500 to 1000 daltons, and incorporates low molecular weight oligosaccharides made up of 3 to 7 glucose and/or fructose units.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white powder
Melting Point:	not determined
Density:	800 kg/m^3
Vapour Pressure:	low (see notes below)
Water Solubility:	800 g/L
Partition Co-efficient (n-octanol/water):	log P_{ow} < 0 at 20°C – see notes below
Hydrolysis as a Function of pH:	none between pH 3.5 – 10 - see notes below.
Adsorption/Desorption:	see notes below

Dissociation Constant: not applicable - see notes below

Flash Point: not applicable

Flammability: not expected to undergo auto-ignition -

Autoignition Temperature: not determined

Explosive Properties: notified chemical is not explosive

Particle Size:

composition	*particle size (μm)*
100%	< 150
99.6%	< 100
95.0%	< 50
86.0%	< 30
44.0%	< 10

Comments on Physico-Chemical Properties

No vapour pressure data was provided, but the vapour pressure would be very low because of the polarity of the hydroxyl groups on the oligosaccharide units. The high water solubility is as expected for polysaccharides.

The notified chemical is made up of a combination of disaccharides (sucrose and maltose) and the linkages between the individual sugar units are cleaved through an enzymatic reaction in the pH range of 4-9 to produce the monosaccharides glucose and fructose.

Polysaccharides are stable to abiotic degradation under normal environmental pH conditions, but under extreme pH conditions the carbon-oxygen bonds may break. The notifier indicates that based on laboratory bench tests, the new chemical is stable under environmental conditions between pH 3.5 and pH 10.

The notifier indicates that BioEcolia does not dissolve in a lipophilic solvent (n-octanol) so it was not possible to determine an exact partition coefficient. However, the high water solubility is indicative of very low partition coefficient, which the notifier indicates as less than zero.

Similarly, the high water solubility and lack of hydrocarbon groups indicates a low K_{oc}. Consequently the compound will not associate with the organic component of soils and sediments, but will remain in the aqueous phase.

The dissociation constant for the new chemical is not applicable in this circumstance as the notified chemical has no acidic or basic functional groups that could dissociate.

4. PURITY OF THE CHEMICAL

Degree of Purity: 100%

Toxic or Hazardous Impurities: none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is a bioselective substrate for bacteria, stimulating the growth of the beneficial cutaneous flora. It is to be used in a large number of face, body and personal care products such as face washes and shampoos. It will be imported at 0.2 tonne per annum for the next five years.

The notified chemical will be imported at 5% concentration in the final product Artistry Absolute Oil Control Foundation SPF15 packed in 30 mL glass bottles contained in a cardboard box.

The product containing the notified chemical will not be reformulated in Australia.

6. OCCUPATIONAL EXPOSURE

The notifier states that one to 2 waterside workers, 2 to 4 transport drivers, 2 to 4 warehouse workers and approximately 1 000 distribution workers (Australia wide) will be handling the product containing the notified chemical. During transport or storage of cardboard boxes containing the notified chemical occupational exposure may occur only in the event of an accidental spillage.

Since the notified chemical is imported in a ready-to-use final product and no reformulation is carried out in Australia no other form of occupational exposure is expected.

The notifier does not indicate if the product will be used in beauty parlours.

7. PUBLIC EXPOSURE

The notified chemical will enter the public domain in face, body and personal care products at a low concentration (approximately 5%). Although members of the public may have dermal and eye contact (eg while using shapoos) with the notified chemical, exposure is likely to be minimal because of the low concentration of the notified chemical in the products. The potential for public exposure to the notified chemical during transport and use or from disposal is assessed as minimal.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier has indicated that the environmental exposure will only occur as a result of accident spills that may occur during transport, storage and handling of the notified chemical. Furthermore, the notifier indicates that disposal of any spilt material at the warehouse will be collected and disposed of by a licensed waste contractor. Domestic disposal would be via household garbage collection and would involve slow degradation in a landfill through biological processes. However, ultimately the notified chemical will be released to the environment via the sewer.

The notifier estimates that 1% (2 kg/per year) of the imported volume of BioEcolia may be accidentally spilt at the warehouse.

BioEcolia makes up 5% of the final product. Two percent of this (approximately 0.2 kg/year) will remain in the bottle after emptying, and disposed of to landfill via domestic garbage collection. The remaining notified chemical (198 kg/year) will be released to domestic sewer systems when excess skin care product is washed off following application.

Since the cosmetic product will be sold throughout Australia, release will be widespread and diffuse at very low levels. Even when placed into landfill, the high solubility of the chemical indicates it will leach rapidly. All released chemical will eventually end up in the water compartment.

Fate

Ready biodegradation data is not required for small volume notifications. However, the polysaccharide nature of the compound indicates at least inherent biodegradibility, consequently, the chemical is not expected to be persistent. The chemical would be degraded to water and carbon dioxide. Furthermore, the potential for bioaccumulation is low due to the high water solubility and the breakdown of the notified chemical into simple sugar components.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of BioEcolia

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2 700 mg/kg	(Periquet, undated)
skin irritation	rabbit	non-irritant	(Saboureau, 1990)
local tolerance	rabbit	very good local tolerance	(Pinon, 1990)
eye irritation	rabbit	non-irritant	(Molina, 1990)
skin sensitisation	guinea pig	non-sensitiser	(Saboureau, 1990)
skin phototoxicity	guinea pig	non-phototoxic	(Saboureau, 1990)

Species/strain:	rat/ Sprague Dawley
Number/sex of animals:	8 males per group (2 groups A and B)
Observation period:	12 days
Method of administration:	a single dose of 2 700 mg/kg to group A, 700 mg/kg to group B, administered by gavage
Test method:	not provided
Clinical observations:	diarrhea was observed up to 3 days in dosed rats; one rat in group A exhibited abnormal excitation for several minutes after administration
Mortality:	none
Morphological findings:	none recorded
LD_{50}:	> 2 700 mg/kg (under the conditions of the study)
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Skin Irritation (Saboureau, 1990)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/sex not specified
Observation period:	3 days
Method of administration:	the test substance (batch number OD2 890131; exact concentration of the notified chemical not known) was applied at 5% in distilled water to a scarified skin site on the right flank of each rabbit; a similar application was done on the left flank on undamaged skin sites; sites were covered with occlusive dressing; after 24 hours the dressing and residual test material were removed
Test method:	France, Decree of February 1st 1982
Result:	there was no erythema or oedema was observed in any of the animals the notified chemical was non-irritant to the skin of rabbits

9.1.3 Skin Irritation – Local Tolerance (Pinon, 1990)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6 – sex not specified
Observation period:	15 days
Method of administration:	2 mL of the notified chemical (reference OD2 890131) was applied at 5% dilution in distilled water daily for 15 consecutive days by a gentle massage to the shaved right flank of each rabbit; the left flank served as a control area; animals were sacrificed on day 15
Comments:	very slight erythema observed in one animal on day 3 was normal on day 4; very slight cutaneous dryness observed in all animals between day 2 and 8; no significant changes to skin elasticity, thickening and speed and quality of hair regrowth was observed; as there was no irritation at the end of day 15 a histological examination was not undertaken
Test method:	France, Decree of December 18th, 1979

Result:	the skin of rabbits demonstrated very good local tolerance to the notified chemical

9.1.4 Eye Irritation (Molina, 1990)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	3 days
Method of administration:	0.1 mL of the notified chemical (reference OD2 890131) at 5% dilution in distilled water was placed in the conjunctival sac of one eye of each rabbit whilst the contralateral eye of each rabbit served as the control
Test method:	France, Decree of September the 21st 1984
Result:	there were no conjunctival, iridal or corneal effects observed in any of the animals the notified chemical was a non-irritant to the eyes of rabbits

9.1.5 Skin Sensitisation (Saboureau, 1990)

Species/strain:	guinea pig/Dunkin Hartley White
Number of animals:	15 in each group (2 groups, one test and one control)
Induction procedure:	reference chemical OD2 890131;test animals: Day 0: three pairs of intradermal injections (0.1 mL) into the scapular region: - Freund's Complete Adjuvant (FCA) 50:50 in isotonic sodium chloride - the notified chemical, diluted to 5% with distilled water - the notified chemical at 5% emulsified in a 50:50 mixture of FCA Day 6 – 10% solution of sodium lauryl sulphate was applied to the injection site

	Day 7- filter paper saturated with the 5% notified chemical was applied to the injection site and held under occlusive dressing for 48 hours during the induction phase the control animals were treated similarly to the test animals omitting the notified chemical from the intradermal injections and topical applications
Challenge procedure:	test and control animals two weeks after topical induction, both groups received on the posterior area of the back 0.5 mL of the notified chemical (2.5% and 1.25%); applications were under semi-occlusive dressing for 24 hours on both sides of the vertebral axis;
Challenge outcome:	no reactions due to sensitisation was observed at 2.5% or 1.25% in any of the animals at the 24 hour or 48 hour reading time
Test method:	similar to OECD guidelines
Comment:	5% proved to be slightly irritant; no macroscopic reactions could be related to sensitisation when used at a 2.5%
Result:	the notified chemical was a non-sensitiser to the skin of guinea pigs at a challenge concentration of up to 2.5%

9.1.6 Skin Phototoxicity (Saboureau, 1990)

Species/strain:	guinea pig/Dunkin Hartley White
Number of animals:	10
Preparation:	72 hours before application of the test substance (reference OD2 890131) the back and the sides of the animals were clipped then hot wax depilated under anaesthesia (note animals with evidence of skin irritation at 72 hours were excluded from the trial)

Method of administration:	before treatment, backs and sides of each animal were divided into 6 areas, to receive chemical or positive control, either alone or in combination with either UVA or UVB irradiation; control areas received either UVA or UVB irradiation alone; 5% aqueous solution of the notified chemical and 8 methoxypsoralen (positive control) were applied at 0.2 mL/cm^2 30 minutes before irradiation the animals were exposed to either UVA and UVB radiation using light tubes; 24 hours after irradiation animals were observed for cutaneous reactions
Irradiation outcome:	a slight irritation was observed on areas irradiated with UVB in untreated and treated areas; under the same conditions, the areas treated with positive control showed major reactions which proved to be significantly higher than those observed with the test substance
Test method:	BIOGIR S.A. Ref. PTC
Result:	the notified chemical was not phototoxic to the skin of guinea pigs

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity (LD_{50} > 2 700 mg/kg) in rats. It was a non-irritant to rabbit skin and eye and a non-sensitiser to the skin of guinea pigs. It was non-phototoxic to guinea pig skin and was shown to be well tolerated on rabbit skin.

The notified chemical cannot determined to be a hazardous substance under NOHSC *Approved Criteria for Classifying Hazardous Substances* on the basis of data supplied on acute oral toxicity, skin and eye irritation and skin sensitisation (National Occupational Health and Safety Commission, 1994a).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The new chemical does not present a hazard to the environment when manufactured as described and used in the indicated manner. Most chemical will end up in the sewerage system where it will undergo degradation processes to form carbon dioxide and water.

The chemical or its degradation products are unlikely to be toxic to aquatic organisms, but in any case all releases of the chemical will be widespread and diffuse at very low concentrations.

The notifier has calculated the mean nationwide Predicted Environmental Concentrations (PEC) in sewage treatment plant effluent as 0.16 g/L. Calculations were based on 100% discharge of the notified chemical into Australian domestic sewers (*i.e.* 198 kg/year) and assume an average of 190 L/person/day of water released to sewer, with a national population of 18 million people. All though some chemicals can be toxic to aquatic organisms at low concentrations, sugars such as sucrose and maltose are not expected to be toxic. The risk posed to the aquatic environment is considered to be extremely low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

On the basis of the submitted toxicological data the notified chemical is unlikely to exhibit acute toxicity, skin or eye irritation or skin sensitisation. It is also not considered to be phototoxic and has been shown to be well tolerated on the skin of experimental animals. No testing on humans was reported. The notified chemical would not be classified as a hazardous substance (NOHSC, 1994a) on the basis of the acute oral toxicity, skin and eye irritation and skin sensitisation data provided.

The risk of exposure to workers involved in transport, storage and distribution is considered to be minimal. Even in the event of a spill the risk of adverse health effects to workers is low because high level of exposure are unlikely to occur, given the nature of the packaging and the concentration of chemical (5%). In any event, the chemical doe not exhibit any systemic or topical health effects. The Material Safety Data Sheet (MSDS) indicates the chemical may cause eye irritation through abrasive action. This is not expected to be of relevance to workers handling the packaged cosmetic product.

Since the notified chemical is imported in a ready-to-use final product and no reformulation is carried out in Australia and use in beauty parlours has not been reported, no other form of occupational exposure is expected.

Although members of the public will make dermal and possible eye contact with notified chemical, exposure is likely to be negligible because of the low concentration of the notified chemical in the consumer products (approximately 5%) and small volume of use in Australia (<1 tonne/annum).

13. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994b).

The MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

14. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- Spillage of the notified chemical should be avoided. Spillage should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(1) of the Act, secondary notification of the notified chemical will be required if the method of use changes in such a way as to greatly increase the environmental exposure of the notified chemical, particularly to natural waters, or if additional information becomes available on adverse environmental effects of the chemical. Under subsection 64(2) of the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under the subsection arise.

16. REFERENCES

Molina J.F. (1990) Assessment of Ocular Tolerance in Rabbit Index of Ocular Irritation, Oligosaccharides Pre-Probiotiques, Reference No. 361002.

National Occupational Health and Safety Commission (1994a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

Periquet G. (undated) Preliminary Study of the Acute Toxicity of the Product Oligosaccharides Ref. 900605 in Rats.

Pinon J.F. (1990) Assessment of Local Tolerance by Repeated Cuntaneous Applications in Rabbit During 15 Days, Oligosaccharides Pre-Probiotiques, Ref OD2 890131.

Saboureau D (1990) Assessment of Sensitising Power in Albino Guinea Pig Maximisation Test According to Magnusson and Kligman, Oligosaccharides Pre-Probiotiques Ref. OD2 890131.

Saboureau D (1990) Evaluation of Phototoxic Power by Topical Applications in the Albino Guinea Pig, Oligosaccharides Pre-Probiotiques Ref. OD2 890131.

Saboureau D. (1990) Assessment of Cutaneous Tolerance in Rabbits Index of Primary Cutaneous Irritation, Oligosaccharides Pre-Probiotiques Ref. OD2 890131.