



BIOLIN/P

Artn: 600233

PRODUCT DOSSIER

1. Product identity:

1.1 Product group:

Active Ingredient

1.2 Product description:

A prebiotic sugar extract from the chicory / sun root.

It is a food supplement for the protective skin microbiota, while the foreign and often harmful organism can not digest BIOLIN. In this way the skin microbiota is favoured over the foreign microorganisms.

In the presence of BIOLIN the skin microbiota will recover faster, while the harmful ones are reduced. BIOLIN avoids skin redness and diaper rash.

It is an essential ingredient for the intimate female hygiene as it balances the protective lactobacilli bacteria.

Clinically tested for baby care and intimate hygiene.

Composition: a mixture of poly- and oligosaccharides.

1.3 Composition:

INCI	%	Cas n°
INULIN	>80	9005-80-5
ALPHA-GLUCAN OLIGOSACCHARIDE	<20	27707-45-5

CTFA	%	Cas n°
INULIN	>80	9005-80-5
ALPHA-GLUCAN OLIGOSACCHARIDE	<20	27707-45-5

1.4 Additives:

Not present

1.5 Allergenic ingredients:

Not present

1.6 Origin and function:

INCI (CTFA):	Origin	Function
INULIN	Vegetable	SKIN CONDITIONING
ALPHA-GLUCAN OLIGOSACCHARIDE	Vegetable	SKIN CONDITIONING



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2. Production process information:

Inulin: extraction from Cichorium Intybus (chicory) / Helianthus tuberosus (sun) root.

Alpha-Glucan Oligosaccharide: enzymatic polymerisation from sucrose and maltose involving glucosyl transferase. The sucrose is extracted from Beta Vulgaris (sugar beet). The maltose is extracted from Triticum Vulgaris (wheat). The enzyme is derived from malt.

2.1 Irradiation: Yes No

2.2 Additional information:

See file: ProdProc-BiolinP-2012.pdf

3. Impurities:

3.1 Heavy metals:

Name	Value
Total	< 20 ppm

3.2 Pesticides:

Not expected to be present.

3.3 CMR impurities:

Not expected to be present.

3.4 Prohibited impurities:

Not expected to be present.

3.5 Other impurities:

3.5.1 Residual solvent

Not expected to be present.

3.5.2 Residual monomers

Name	Value
Carbohydrates (Glucose+Fructose+Sucrose)	<=70000 ppm

3.5.3 Residual reactants

Not expected to be present.

3.5.4 Polyacrylic Aromatic Hydrocarbons

Not expected to be present.



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3.5.5 Others

Name	Value
1,4-Dioxane	- Not expected to be present.
Ethylene Oxide	- Not expected to be present.
Diethylene Glycol	- Not expected to be present.
Dioxin	- Not expected to be present.
Sulfite	- Not expected to be present.
Aromatic Amines	- Not expected to be present.
Acrylamide	- Not expected to be present.
Nitrosamines	- Not expected to be present.
Monochloroacetic Acid	- Not expected to be present.
Dichloroacetic Acid	- Not expected to be present.
Formol	- Not expected to be present.
Formaldehyde	- Not expected to be present.
Phthalates	- Not expected to be present.
Glycol Ether	- Not expected to be present.
Bisphenol A	- Not expected to be present.
Lactose	- Not expected to be present.
Proteins	- 0 g/100 g d.m. - According to applicable rounding rules in EU and US

4. Physio-chemical characteristics:

4.1 Specification

Parameter	Specification
Appearance @ 20°C	Powder
Odour	Almost odourless
Colour	White
Dry matter	95 - 98.5 % *calculated
pH @ 5% solution @ 20°C	5 - 7.5
Active matter	92 - 98 % *calculated



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4.2 Typical Microbiology:

Parameter	Value
Total Vival Count (TVC)	<100 CFU/g
Yeast	<10 CFU/g
Moulds	<10 CFU/g
Bacteria - Gram negative	Absent / 1g
Candida Albicans	Absent / 1g
Enterobacteriaceae	Absent / 1g
Escherichia Coli	Absent / 1g
Pseudomonas Aeruginosa	Absent / 1g
Staphylococcus Aureus	Absent / 1g

4.3 Fatty acids distribution:

-

4.4 Typical Properties:

Parameter	Value
Ionicity	Non-ionic

4.5 Quality of the product:

Type	Details
Natural Index (acc. to ISO 16128)	NI=0.8
Natural Origin Index (acc. to ISO 16128)	NOI=1
Organic Index (acc. to ISO 16128)	OI=0
COSMOS	Product certified, see current certificate for details.
NaTrue	Product certified, see current certificate for details.

5. Formulation guideline:

5.1 Solubility:

Name	Solubility
Water	Soluble
Glycerine	Insoluble
Propylene glycol	Insoluble
Ethanol	Insoluble
Mineral oil	Insoluble
Soya oil	Insoluble
Cyclomethicone	Insoluble
Octylstearate	Insoluble
Dimethicone	Insoluble
Oil	Insoluble



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5.2 Compatibility:

Name	Compatibility
Peroxides	Incompatible
Carbomer	Compatible
Colourants - oil soluble	Compatible
Colourants - water soluble	Compatible
DHA	Compatible
Electrolytes +	Compatible
Electrolytes ++	Compatible
Electrolytes Al/Zr +++	Compatible
Essential oils	Compatible
Hydrogen peroxide	Incompatible
Mineral oils	Compatible
Oxidizing agents	Incompatible
Parfum	Compatible
Plant extracts	Compatible
Preservatives	Compatible
Reducing agents	Incompatible
Silicone oils	Compatible
Synthetic oils	Compatible
Thioglycolates	Incompatible
Vegetable oils	Compatible
Vitamines	Compatible

5.3 pH range:

4.3 - 10.0

5.4 Maximum heating temperature:

< 60 °C - During 8 hours.

5.5 Incorporation:

Product has to be added to the water phase.

5.6 Dosage:

Application	%
All cosmetic applications	0.5 - 5

5.7 Additional information:

None



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5.8 Demonstration formulations

See files:

- Form-DualActionAcneLotion-AL081012D-Distributor.pdf
- Form-NippleCream-NC-180707-C-distributor.pdf
- Form-ProtectiveHygienicGel-BGD100427A-Distributor.pdf

6. Product properties:

- Balances the natural protection of the skin
- Prebiotic chicory sugar
- Skin prebiotic
- Helps avoid discomfort
- Prevents diaper rash
- Prevents intimate discomfort rash

7. Product application:

- Baby products
- Intimate hygiene
- Diabetic skin products
- Delicate skin products



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8. Product claims:

Claim	Test method	Type	Application	Comments
Prevention of diaper rash	Dermatological assessment	In-Vivo	Leave on	2% Biolin P
Prevention of intimate discomfort	Dermatological assessment	In-Vivo	Rinse off	2% Biolin P
Normalizing diabetes skin	Dermatological assessment	In-Vivo	Leave on	

Protocols

See files:

- Protocol-UsertestDiaperRash-1807.pdf
- Protocol-UsertestFeminineWash-1807.pdf
- Protocol-CT-Prebiotics-1810.pdf

Brochures

See files:

- Derm-Biolin-Baby.pdf
- Derm-Biolin-Feminine.pdf
- Mark-Story-BiolinP-2012.pdf
- Mark-Biolin-2102.pdf

Presentations

See files:

- Pres-Biolin-1912.pdf

9. Logistics:

9.1 Shelf life:

48 months

9.2 Storage information:

Store in a dry, cool and well-ventilated area below 35°C.
Relative humidity should not exceed 60%.

9.3 Customs Tariff Code (HS)

17029095

9.4 Country of origin:

NL

9.5 Packages information:

Quantity (kg)	Type:	Package material:	Amount EURO Pallet	Amount Block Pallet
1 kg	Bucket	PP	NR	NR
5 kg	Bucket	PP	NR	NR
20 kg	DRUM	HDPE	480 kg	720 kg



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10. Regulation:

10.1 Cosmetic regulation status

Country	Status	Comments
China	Compliant	IECSC- Chinese Chemical Inventory of Existing Chemical Substances
EU	Compliant	Regulation (EC) No 1223/2009
USA	Compliant	FD&C Act – 21 CFR 700 to 740
Japan	Compliant	ISHL- Industrial Safety and Health Law
Canada	Compliant	DSL - Canadian Domestic Substances List
Australia	Compliant	AICS - Australian Inventory of Chemical Substances
Korea	Compliant	ECL- Korean Existing Chemicals List
US California	Compliant	Regulation California Proposition 65
Mexico	Compliant	-
Middle East	Compliant	-
Russia	Compliant	-
Turkey	Compliant	-
New Zealand	Compliant	-
Mercosul: Argentina, Paraguay, Uruguay, Venezuela, Brazil	Compliant	Southern Common Market
South Africa	Compliant	-
Asean: Burnei Darussalam, Cambodia, Indonesia, Laos, Myanmar, Philipipines, Singapore, Thailand, Vietnam	Compliant	ASEAN Cosmetic Directive

10.2 REACH registration status

Ingredient	Status
ALPHA-GLUCAN OLIGOSACCHARIDE	Exempt: Polymer - exempt according to Article 2, paragraph 9. Monomers: Glucose, listed in Annex IV of Regulation 1907/2006
INULIN	Exempt: Annex V, art 2(7)(b), point 9 of EC 987/2008 (as composed of the natural polymer, chemically non-modified, ingredients). Monomers: Glucose, Fructose listed in Annex IV of Regulation 1907/2006



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11. Toxicological profile:

Type	Result	Comments
Acute oral toxicity	LD50 > 5.000 mg/kg	
Skin irritation	Non irritant	tested at 25%
Skin sensitization	Non sensitizing	tested at 10%
Eye irritation	Non irritant	tested at 25%
Mutagenicity	Non mutagenic	
Phototoxicity	Non phototoxic	tested at 25%
Genotoxicity	Non Genotoxic	
GRAS status	Generally recognized as safe	

Type	Value	Unit	Comments
Percutaneous Penetration	5	%	Derived from individual ingredients.

Type	Value	Unit	Comments
NOAEL	1900	mg/kgbw/d	Derived from individual ingredients.

Reports

See files:

- ToxReport-EyeIrritation-Biolin-0608.pdf
- ToxReport-Phototoxicity-Biolin-0707.pdf

12. IFRA Statements:

Not relevant.

13. Statements:

Allergens	The substances suspected to be allergenic and listed in Annex III of EC 1223/2009 are below detection limit.
CMR	Based on our current knowledge of the production process, the used raw materials, the produced by products, the impurities and the equipment used we do not expect CMR substances 1A, 1B and 2 according to EC 1272/2008 Annex VI present in the product. The product is fully in compliance with article 15 of EC 1223/2009.
Animal Testing	This raw material has not been tested on animals for cosmetic purposes after the date 11/03/2009. This raw material is in compliance with article 18 EC 1223/2009.
Annex II ingredients	This product does not contain any of the substances listed in Annex II ('List of substances prohibited in cosmetic products') of the European Commission's Cosmetic Ingredient Database (CosIng).



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BSE/TSE	This raw material is not of animal origin. During production, storage and transport there is no contact with any bovine or other animal material and a cross contamination is excluded. Therefore the requirements of Comm. Dirc 1999/82/EEC, CPMP/BWP/1230/98, Ph.EUR. Suppl. 2000:5.2.8 are not applicable.
Children Exploitation	No children are involved in the production process of this material. We strictly prohibit the use of child labour under the age of 15 or under the age for completion of compulsory education, whichever is higher, per the ILO Minimum Age Convention No. 138 (1973) and prohibit work that would harm the health, safety or morals of children per the ILO Worst Forms of Child Labor Convention No. 182 (1999).
CITES Vegetal Species	This raw material does not contain components regulated by CITES Vegetal Species.
Conflict Minerals	This raw material does not contain Conflict Minerals from countries which are known as conflict areas mentioned by the Dodd-Frank Act Section 1502. We are in a constant contact with our suppliers to ensure that the requirements of Conflict Free Minerals are fulfilled within the supply chain. It is our intention not to accept tin, tantalum, tungsten, gold or theirs derivatives known to originate from conflict areas.
CoRAP	This raw material does not contain any substances included in the CoRAP list.
Gluten	This raw material is free from gluten.
GMO	This raw material does not contain ingredients derived from GMO sources. However relevant thresholds for adventitious or technically unavoidable cross-contamination as laid down in 1829/2003/EC are accepted.
Green Chemistry	This raw material is produced according to the guidelines of 12 principals of green chemistry.
Halal	All ingredients used in the production process of this raw material are non-animal based and/or do not contain any animal impurities. The following ingredients have been explicitly excluded during the complete production process: - swine/pork and its by-products, or ingredients based on swine/pork, - animals improperly slaughtered or dead before slaughtering, - animals killed in the name of anyone else than Allah, - ethanol (alcohol) or drugs, - carnivorous animals, - birds of prey, - land animals without external ears, - blood, blood by products and blood derived ingredients. This raw material is not Halal certified.
Impurities	The presence of any impurities is non-intended and technically unavoidable in good manufacturing practice. We hereby declare that all relevant and legal relevant ingredients, impurities, cross contaminants, by-products, residual solvents, additives and micro-organisms are declared and elaborated in this product dossier. All other ingredients, impurities, cross contaminants, by-products, residual solvents, additives and micro-organisms, which have not been mentioned and elaborated in this dossier are not relevant and are by consequence not present in the product.



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Kosher	This raw material is not derived from, nor does it contain pork and/or pork derivatives. This product is not Kosher certified.
Microplastic	This raw material does not contain: <ul style="list-style-type: none">- microplastic ingredients listed in UNEP report 'Plastic in Cosmetics', 2015,- microplastic ingredients listed in TAUW-report "Test to assess and prevent the emission of primary synthetic microparticles"- microplastic ingredients according to the definition of Plastic Soup Foundation- microplastic ingredients according to the definition of ECHA proposal Annex XV (microplastic' means particles containing solid polymer, to which additives or other substances may have been added, and where $\geq 1\%$ w/w of particles have (i) all dimensions $1\text{ nm} \leq x \leq 5\text{ mm}$, or (ii) a length of $3\text{ nm} \leq x \leq 15\text{ mm}$ and length to diameter ratio of >3. Natural polymers that have not been chemically modified are excluded, as are polymers that are (bio)degradable (according to the criteria set out in Appendix X of the proposal) or soluble (according to the criteria set out in Appendix Y on the proposal).
Nagoya	The best of our knowledge, this raw material is conform to the Nagoya Protocol Regulation (EU) N°511/2014 (EU CM-ABS Regulation) on access to genetic resources and the fair and equitable sharing of benefit arising from their utilization.
Nanomaterials	This raw material is not classified as nano-material according to COLIPA's guidance SCCS/1484/12, EU Cosmetic regulation 1223/2009, French Decree n° 2012-232
Oral Care	This raw materials is GRAS approved, has no acute, nor systemic oral toxicity and is not cariogenic. Therefore, this raw material is suitable and safe for oral care.
Palm Origin	This raw material does not contain and is not derived from palm and/or palm kernel oil.
SVHC	This raw material does not contain substances listed as Substances of Very High Concern under the REACH Regulation.
TSCA	This raw material is not listed in the TSCA Chemical Substance Inventory.
Vegan	This raw material neither contains animal and/or animal derived ingredients, nor has it been in contact with animal and/or animal derived ingredients. To the best of our knowledge, this raw material fulfills the requirements set by the Vegan Society.
VOC	This raw material does not contain substances listed as Volatile Organic Compounds.

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