TECHNICAL INFORMATION FILE

PRODUCT: **NECTARIA LITHOPS 01**

Date: April 2021

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Version: 1. Date: 2021/04/19

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1. PRODUCT IDENTIFICATION

PRODUCT	NECTARIA LITHOPS 01
CODE	PhyLit-PG-01
INCI DECLARATION	Lithops Pseudotruncatella Callus Lysate, Glycerin, Pentylene Glycol, Cyamopsis Tetragonoloba (Guar) Gum, Xanthan Gum, Phytic Acid, Water (Aqua)
DESCRIPTION	Suspension containing *Lithops pseudotruncatella* glycoconjugates in glycerine

2. PRODUCT SPECIFICATIONS

ASSAY	SPECIFICATION	METHOD
Organoleptic exam		
APPEARANCE	Viscous suspension [1][2]	IOCQ02/003
COLOUR	Off white – greenish [1]	IOCQ02/004
ODOUR	Characteristic	IOCQ02/005
Physicochemical Parameters		
pH	2.0 - 3.5	IOCQ02/001
DENSITY	1.10 - 1.30 g/mL	IOCQ1012
FRUCTOOLIGOSACCHARIDES	> 1500 mg/l	IOCQ02/44
PROTEIN CONTENT	> 150 mg/l* (* of which 20% are GLYCOPROTEIN)	IOCQ02/45
POLYPHENOLICS	> 100 mg/L	IOCQ02/51
Microbiological Parameters		
TOTAL AEROBIC MICROBIAL COUNT	≤ $1x10^2$ CFU/g [3]	UNE-EN ISO 21149
TOTAL YEAST AND MOULD COUNT	≤ $1x10^1$ CFU/g	UNE-EN ISO 16212
PATHOGENIC GERMS		
Escherichia coli	Absence in 1g	UNE-EN ISO 21150
Staphylococcus aureus	Absence in 1g	UNE-EN ISO 22718
Pseudomonas aeruginosa	Absence in 1g	UNE-EN ISO 22717
Candida albicans	Absence in 1g	UNE-EN ISO 18416

Remarks

[1] This is a natural product, so colour or transparency may evolve slightly after production without affecting its properties.
[2] After some time, a precipitate may appear. This can be solved by shaking well before use.
[3] According to ISO 17516:2014 (and according to USP Chapter 61 or EP Chapter 2.6.12) due to inherent variability of the plate count method results are considered out of limit if > 200 CFU/g. Our specific test report does not obviate the need to test products for the own intentions and purposes of your company.

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3. PRODUCT COMPOSITION

INCI	%	CAS No	EC No
Lithops Pseudotruncatella Callus Lysate	50.00	--	--
Glycerin	44.20	56-81-5	200-289-5
Pentylene Glycol	5.00	5343-92-0	226-285-3
Cyamopsis Tetragonoloba (Guar) Gum	0.25	9000-30-0	232-536-8
Xanthan Gum	0.25	11138-66-2	234-394-2
Phytic Acid	0.15	83-86-3	201-506-6
Water (Aqua)	0.15	7732-18-5	231-791-2

4. ORIGIN

INCI	ORIGIN	PLANT	COUNTRY OF ORIGIN
Lithops Pseudotruncatella Callus Lysate	Vegetal	*Lithops Pseudotruncatella*	Spain
Glycerin	Vegetal	*Brassica napus*	Germany
Pentylene Glycol	Vegetal	*Saccharum officinarum* *Zea mays*	South Africa China
Cyamopsis Tetragonoloba (Guar) Gum	Vegetal	*Cyamopsis tetragonoloba*	India
Xanthan Gum	Biotechnological	Not applicable	Austria
Phytic Acid	Vegetal	*Oryza sativa*	Japan
Water (Aqua)	Mineral	Not applicable	--

5. STORAGE

To be stored in hermetically closed vessels at a temperature of 4 - 8 ºC and protected from direct light and humidity.

Before using this product allow it to reach room temperature (15-25ºC) and shake well before use.

6. RECOMMENDED RETEST DATE

12 months after production, if kept at the recommended storage conditions and the original packaging. We recommend maintaining the container/package well closed as long as possible and observe good hygienic practices in handling.

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7. CUSTOMS TARIFF NUMBER / HS CODE / TARIC CODE

1302.19.70.00

8. REGULATORY INFORMATION

The product is compliant with the following rules and regulations:

European Union	Cosmetic Regulation (EC) No 1223/2009: Annex II – substances which should not be used in cosmetics Annex III – restricted substances Annex IV – colouring agents Annex VI – UV-filters
U.S.A.	21 CFR Food and Drugs. Provisions § 700.11 to § 700.16 California Proposition 65
Japan	Standard for Cosmetics in accordance to Pharmaceutical Affairs Law (Law No 145 of 1960) Appendix 1. Prohibited materials Appendix 2, 3 and 4. Restricted ingredients

The product complies with the following status:

REACH *Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)*	We hereby confirm that each ingredient of our product manufactured in and/or imported into the European Community is taken into account in fulfilment of the requirements given by the REACH Regulation (EC) No 1907/2006. We hereby confirm that the product does not contain substances listed in the current Candidate List of substances of very high concern (SVHC) at concentrations of 0.1 % w/w or higher. Furthermore, the product does not contain substances listed in REACH Annex XIV (Authorisation List) nor in REACH Annex XVII (Restricted Substances List) at concentrations of 0.1 % w/w or higher.
NAGOYA PROTOCOL *Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*	Exempt
CITES *Convention on International Trade in Endangered Species of Wild Fauna and Flora*	Not listed
COSMOS	Certifiable
SKIN MICROBIOME	Excellent skin microbiome compatibility
ISO 16128	Natural origin index: 99.6 %
ANIMAL TESTING	According to Cosmetic Regulation (EC) No 1223/2009, no animal testing has been carried out on the product since 11/03/2009.

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NON-ANIMAL ORIGIN & TSE/BSE	The product is free from animal-derived ingredients, and therefore there is no risk of TSE/BSE.

Based upon our production process and the data provided by our suppliers regarding the raw materials used, we have reason to answer the following questions as follows:

Are there any allergens from the 26 listed in the Cosmetic Regulation (EC) No 1223/2009, Annex III, No 67 - 92?	**No**
Are there any CMR ingredients (Carcinogenic, Mutagenic or Toxic to Reproduction substances) present, according to Regulation (EC) No 1223/2009, Article 15?	**No**
Are there any Nanomaterials, according to Cosmetic Regulation (EC) No 1223/2009?	**No**
Are there any Residual organic solvents / VOC (Volatile Organic Compounds), according to CPMP/ICH/283/95? *Class 1 - solvents to be avoided* *Class 2 - solvents to be limited* *Class 3 - solvents with low potential*	**No**
Are there any residual starting materials of concern, e.g. Ethylene Oxide, Diethanolamine, Monomers?	**No**
Are there any by-products from manufacturing processes, e.g. 1,4-Dioxane, Nitrosamines, PAH (Polycyclic Aromatic Hydrocarbons)?	**No**
Are there any contaminants, e.g. Phthalates, BHT/BHA, Free Amines, Aflatoxins?	**No**
Are there any Heavy Metals (lead, arsenic, cadmium, mercury, antimony, chromium, cobalt, nickel, barium, selenium, and copper)?	**Trace amounts may be present**
Are there any additives?	**No**
Are there any pesticides?	**No**
Are there any palm oil or derivatives?	**No**
Are there any GMO organisms, plants or enzymes?	**No**
Is there any gluten?	**No**

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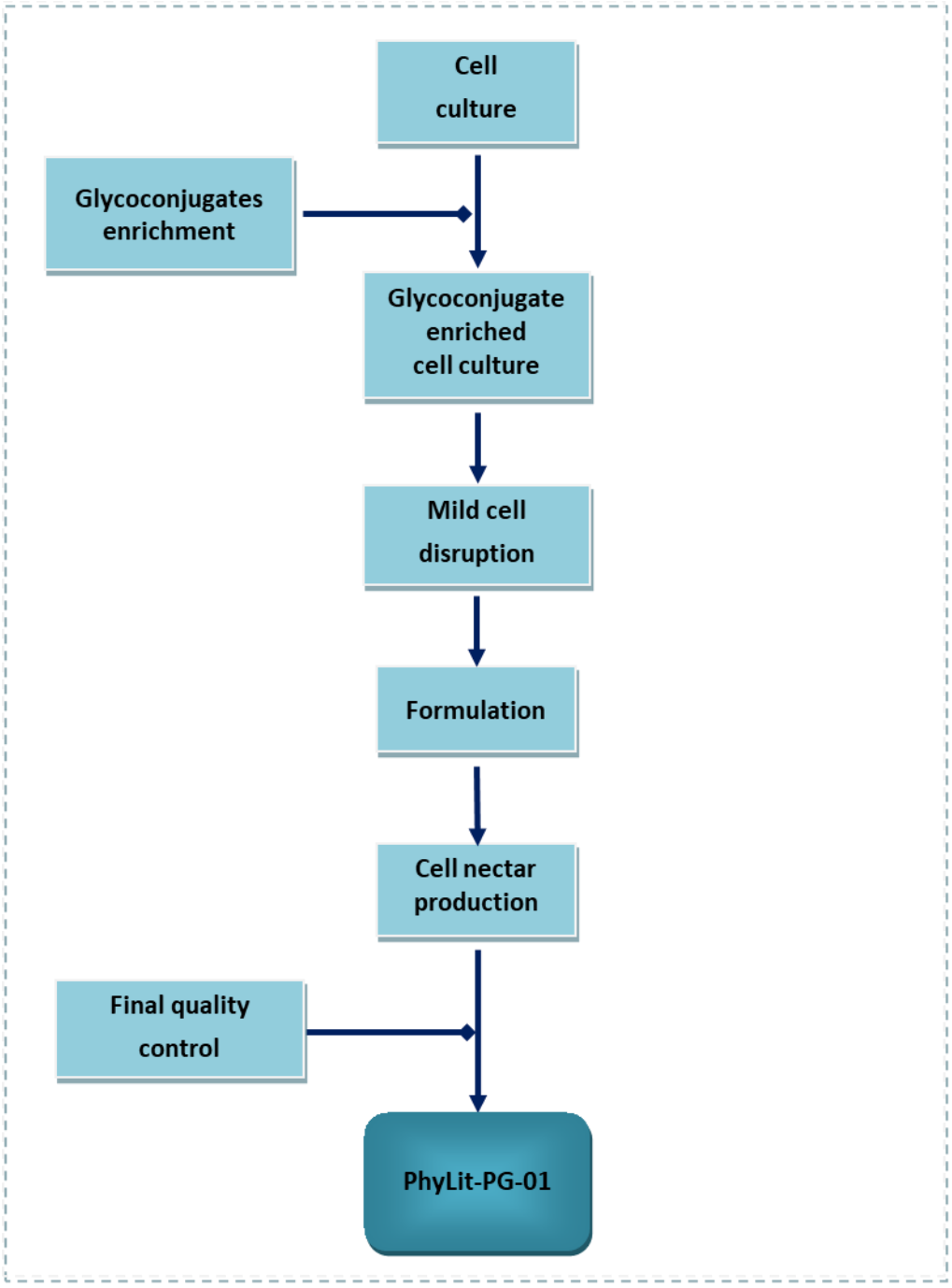
9. MANUFACTURING FLOWCHART

The product NECTARIA LITHOPS 01 is manufactured according to the following standard protocol:



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10. TOXICOLOGICAL INFORMATION

In vivo TESTING

Skin tolerance

This Patch test intended to confirm, in a panel of healthy human subjects, the skin compatibility of NECTARIA LITHOPS 01, after a single application under maximising and experimental conditions, creating a certain occlusion and favouriting the penetration of the product through the skin, according to the recommendations of Colipa (August 1997) "guidelines for the assessment of human skin compatibility".

Under the experimental conditions adopted NECTARIA LITHOPS 01 **has very good skin compatibility**.

Skin sensitization (Hypoallergenicity)

The HRIPT intended to confirm the skin compatibility and the absence of allergenic potential of several cosmetic products including NECTARIA LITHOPS 01, after repeated application to the skin under exaggerated experimental conditions creating a certain occlusion and favouriting the penetration of the product through the skin, according to an adaptation from the methodology described by Marzulli and Maibach (Human Repeated Insult Patch Test for delayed contact hypersensitivity).

Under the experimental conditions adopted, NECTARIA LITHOPS 01 **induced no reaction of irritation** and **has a very good skin compatibility**. Moreover, no allergic reaction was detected, thus, NECTARIA LITHOPS 01 may be considered as **hypoallergenic** under this specific context.

Photo-patch test

This Photo-Patch test intended to check the absence of phototoxic potential of NECTARIA LITHOPS 01, after a single application to the skin under exaggerated experimental conditions.

The product was applied, once, to the skin under the patch. After removal of the patch, the area was exposed to UVA radiation.

Under the experimental conditions adopted NECTARIA LITHOPS 01 did not exhibit any evidence of phototoxic potential.

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In vitro TESTING

Evaluation of skin irritation

Evaluation of skin irritation potential (production of reversible damage to the skin following the application of a chemical) of NECTARIA LITHOPS 01 by measurement of cytotoxic effect on reconstructed human epidermis (RHE) model according to the OECD method 439 (OECD guideline for the testing of chemicals – in vitro skin irritation).

According to the experimental conditions of the study, the product NECTARIA LITHOPS 01 is considered **NON-IRRITANT for the skin**.

Evaluation of ocular irritation

Assessment of the ocular irritation potential of NECTARIA LITHOPS 01 by Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage according to OECD 492.

According to the experimental conditions of the study NECTARIA LITHOPS 01 resulted to be **NOT EYE IRRITANT**.

Mutagenicity test

Assessment of mutagenic potential according to OECD 471 Bacterial Reverse Mutation Test (Ames test).

In the performed experimental conditions, the product NECTARIA LITHOPS 01 is considered **NON MUTAGENIC**.

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11. APPLICATION DATA

Processing

NECTARIA LITHOPS 01 can be formulated in many kinds of emulsions (O/W, W/O), as well as in aqueous gels, serums and lotions, including hydro-alcoholic lotions with up to 30 % of ethanol.

We recommend adding it in the final step of the manufacturing process, preferably under 40ºC, i.e., during the cooling phase. Temperatures of up to 75ºC for a short period of time do not affect the stability of the product.

After some time, a precipitate may appear. This is completely normal, and it can be solved by shaking well before use.

No incompatibilities have been reported: it is compatible with a wide range of thickeners (e.g., from polyacrylates to natural thickeners such as xanthan gum); it is compatible with a wide variety of preservative systems, surfactants, sun filters (physical and chemical), pigments and with other ingredients commonly used in skin care formulations (hyaluronic acid, salicylic acid, etc). The addition of NECTARIA LITHOPS 01 does not affect the pH or the viscosity of final cosmetic formulations at the recommended use concentrations. Therefore, the product NECTARIA LITHOPS 01 can be formulated in a wide range of skin care formulations.

Solubility

The product NECTARIA LITHOPS 01 is dispersible in water and ethanol solutions up to 30% of ethanol.

Recommended pH range

NECTARIA LITHOPS 01 can be formulated at a pH range of 2.0 - 9.0 in final cosmetic formulations.

Dosage

A dosage of 1 - 3 % of NECTARIA LITHOPS 01 is recommended in final cosmetic formulations.

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ANNEX I.
GUIDELINE FORMULATIONS

Disclaimer: The information contained herein is meant to demonstrate how our products can be used. The given data, including claims and procedures, are suggestions without any guarantee, aimed at supporting customers' development. Any product manufactured corresponding to the present recipe is used at own risk and may require additional testing prior to marketing in order to comply with local regulations.

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FORMULATION F19001.04: Cream containing 1.5% NECTARIA LITHOPS – *IN VIVO*

INCI	% (w/w)
A	
WATER (AQUA)	67.93
CARBOMER (CARBOPOL® 934 POLYMER)	0.50
PROPANEDIOL	4.20
GLYCERIN	1.00
POTASSIUM CETYL PHOSPHATE (MASSOCARE CPH-K)	0.30
B	
C12-10 ACID PEG-8 ESTER (EMULPHARMA® 15)	4.10
GYCERYL STEARATE SE (MASSOCARE GMO SE)	3.10
CAPRYLIC/CAPRIC TRIGLYCERIDE	5.20
CETEARYL ETHYLHEXANOATE (MASSOCARE CO)	4.20
DECYL OLEATE (MASSOCARE DO N)	5.70
C	
SODIUM HYDROXIDE	0.21
WATER (AQUA)	0.94
D	
PRESERVATIVE	1.00
TOCOPHEROL, BETA-SITOSTEROL, SQUALANE (TOCOBIOL® C)	0.02
E	
FRAGANCE/PARFUM	0.10
NECTARIA LITHOPS	**1.50**

APPEARANCE:

White bright emulsion

SPECIFICATIONS:

PH: 5.5-6.5

PROCEDURE:

1. Heat to 75ºC and disperse the carbomer adding it slowly. Add the other components of phase A.
2. Heat phase B to 75ºC.
3. Add phase B over phase A and homogenize for 10 minutes.
4. Pre-dissolve phase C and add it over A+B.
5. Cool to 40 degrees. Add consecutively components of phase D and E and stir for 10 minutes.

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FORMULATION F19001.04: Cream containing 1.5% NECTARIA LITHOPS – *IN VIVO* - PLACEBO

INCI	% (w/w)
A	
WATER (AQUA)	67.93
CARBOMER (CARBOPOL® 934 POLYMER)	0.50
PROPANEDIOL	4.20
GLYCERIN	1.00
POTASSIUM CETYL PHOSPHATE (MASSOCARE CPH-K)	0.30
B	
C12-10 ACID PEG-8 ESTER (EMULPHARMA® 15)	4.10
GYCERYL STEARATE SE (MASSOCARE GMO SE)	3.10
CAPRYLIC/CAPRIC TRIGLYCERIDE	5.20
CETEARYL ETHYLHEXANOATE (MASSOCARE CO)	4.20
DECYL OLEATE (MASSOCARE DO N)	5.70
C	
SODIUM HYDROXIDE	0.21
WATER (AQUA)	0.94
D	
PRESERVATIVE	1.00
TOCOPHEROL, BETA-SITOSTEROL, SQUALANE (TOCOBIOL® C)	0.02
E	
FRAGANCE/PARFUM	0.10
WATER (AQUA)	**1.50**

APPEARANCE:

White bright emulsion

SPECIFICATIONS:

PH: 5.5-6.5

PROCEDURE:

1. Heat to 75ºC and disperse the carbomer adding it slowly. Add the other components of phase A.
2. Heat phase B to 75ºC.
3. Add phase B over phase A and homogenize for 10 minutes.
4. Pre-dissolve phase C and add it over A+B.
5. Cool to 40 degrees. Add consecutively components of phase D and E and stir for 10 minutes.