El Jabón Artesanal
Victor Vicente Cordovilla
C/ Rio Tajo nº 53
18110 Las Gabias, (Granada-España)
Telf. (+34) 637594492
eljabonartesanal@hotmail.com

CERTIFICADO DE ANÁLISIS
BARROS DEL MAR MUERTO

LOTE: 282179/5

Caducidad: 09/2024

Microbiological tests

Parameter	Unit	Measured Value	Uncertainty*	Testing method /Process variance	SL	TT
Total viable count	CFU/g	<1x10¹	-	STN EN ISO 21149	NZ	A
Enterobacteriaceae	CFU/g	<1x10¹	-	STN EN ISO 21528-2	NZ	N
Enterococi	CFU/g	<1x10¹	-	ŠPP.MB.M.043 (ČSN EN ISO 7899-2)	NZ	N
Yeast	CFU/g	<1x10¹	-	ČSN ISO 21527-2	NZ	N
Moulds	CFU/g	<1x10¹	-	ČSN ISO 21527-2	NZ	N
Escherichia coli	without/g	absent	-	STN 56 0100 čl.95	NZ	N
Staphylococcus aureus	-	absent	-	STN EN ISO 22718	NZ	A
Pseudomonas aeruginosa	-	absent	-	STN EN ISO 22717	NZ	A
Yeast genus Candida	-	absent	-	STN EN ISO 18416	NZ	A
Total anaerobic count at 20°C	CFU/g	<1x10¹	-	ŠPP MB.M.032	NZ	N

Physical and chemical tests

Parameter	Unit	Measured Value	Uncertainty*	Testing method /Process variance	SL	TT
pH	-	8,41	2%	ŠPP 001-D	BA	A
Water by Karl Fischer method	%	13,12	1,3%	ŠPP 065-D	BA	N
Sodium chloride	%	8,36	4,1%	ILP-007	BA	N
Nitrogen elementary	%	0,14	2,4%	EN 15 407	BA	A
Sulphur elementary	%	3,2	5,4%	ISO 15 178	BA	A
Aluminium	mg/kg	17500	-	Varian Analytical Methods AES-ICP	TR	N
Arsenic	mg/kg	2,8	20%	LS-PP-CH-2/2	TR	A
Barium	mg/kg	18,4	-	Varian Analytical Methods AES-ICP	TR	N
Calcium	mg/kg	51930	-	Varian Analytical Methods AES-ICP	TR	N
Cadmium	mg/kg	1,6	15%	LS-PP-CH-2/4	TR	A
Cobalt	mg/kg	6,1	-	LS-PP-CH-2/9	TR	N
Chromium	mg/kg	58,6	-	LS-PP-CH-2/5	TR	N
Copper	mg/kg	6,0	-	LS-PP-CH-2/8	TR	N
Iron	mg/kg	8310	-	Varian Analytical Methods AES-ICP	TR	N
Mercury	mg/kg	<0,01	-	LS-PP-CH-30	TR	A
Potassium	mg/kg	6480	-	LS-PP-CH-2/19 Methods AES-ICP	TR	N
Magnesium	mg/kg	26070	-	Varian Analytical Methods AES-ICP	TR	N
Manganese	mg/kg	206	-	Varian Analytica	TR	A
Sodium	mg/kg	18840	-	LS-PP-CH 2/18	TR	N
Nickel	mg/kg	42,4	-	LS-PP-CH-2/10	TR	N
Lead	mg/kg	<0,30	-	LS-PP-CH-2/25	TR	A
Antimony	mg/kg	0,033	-	LS-PP-CH-2/26	TR	N
Zinc	mg/kg	102	-	LS-PP-CH-2/12	TR	N

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FICHA DE SEGURIDAD
BARRO DEL MAR MUERTO

1. Quantitative and qualitative composition of cosmetic product

Ingredient INCI	CAS number	EINECS number	Intended function	Content	Restriction
Limus	---	---	skin conditioning	100,00	---

2. Physical and chemical characteristics and stability of the cosmetic product

2.1 Cosmetic ingredients

Physical-chemical properties of each substance were tested by supplier according their specification and each substance satisfies requirements.

Ingredient	Synonym	Characters
Limus		Naturally occurring substances, silt, a sediment from inland bodies of water

2.3 Stability of cosmetic product

Product doesn`t have any expiration date since the product does not change over time. Product should be stored in a dry place without exposure to direct sunlight in order to avoid micro bacterial growth and the package material from being destroyed.

3. Microbial quality

3.1 Microbial quality of raw materials

Microbial quality of each substance was tested by supplier according its specification and each substance satisfies requirements.

3.2 Microbial quality of cosmetic product

Microbiological properties of cosmetic product were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 34291/2016 with satisfactory results.

Preservation challenge tests were not tested according to the STN EN ISO 29621 because the product is of low microbiological risk.

4. Impurities and traces

4.1 Impurities and traces of raw materials

Each raw material was tested to the content of impurities. Traces were evaluated with regard to the safety of the finished product. In case of material containing traces of prohibited substances, the evidence of their technical unavoidability was tested by supplier.

4.2 Impurities and traces of cosmetic product

Traces of heavy metals were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 34291/2016 with satisfactory results.

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4.3 Packaging of cosmetic product

The primary packaging material is polyethylene packaging material. Material meets the requirements the requirements on the content of dangerous substances. Based on long-term monitoring, back analysis of reference samples showed no signs of reactions between the product and packaging materials at least until the end of the minimum durability of the product. Packaging material was observed by ASSENOVA KREPOST JSC.

Cosmetic product is packaged in packages intended for this use.

5. Normal and reasonably foreseeable use

Product is intended for body care.

6. Exposure to the cosmetic product

a. *The site of application:* Product is applied on the body.
b. *The surface area of application:* 17 500 cm^2.
c. *The amount of product applied:* up to 18.67 g/day.
d. *Duration and frequency of use:* twice a day; washes off.
e. *The normal and reasonably foreseeable exposure route:* body.
f. *The targeted populations:* women, men.

Predictable wrong use: Possible contact with mucous membrane of eye and eye irritation. In case of contact eyes should be washed-off with lukewarm water.

g. *Estimated daily exposure:* 2.79 mg/kg bw/day.

7. Exposure to the substances

Calculated systematic exposure dosage (SED) for individual ingredients:

Ingredient	**SED (mg/kg bw/day)**
Limus	2,79

According to calculated SED, product does not contain components, which may have an influence on user's health.

8. *Toxicological profile of the substances*

Product does not contain components with significant toxicological profile from user's health aspect.

Ingredient with calculated MoS greater than 100 is considered to be safety.

9. Undesirable effects

Undesirable effects are not expected during normal and reasonably foreseeable use of cosmetic product.

10. Information on the cosmetic product

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Tests were performed on group of volunteers. All of the participants fulfilled all the criteria for assign to the study, were clearly informed regarding the study and gave their written informed consent before participation in the study.

Product was applied as a mixture with water on the forearm of volunteers repeatedly.

All of the volunteers were visually controlled in periodical intervals since application.

Visually were assessed viewable skin changes on application area, for example redness.

Volunteers subjective commented product properties like unpleasant feelings, itching and burning on application area.

Information sources:

- SCCS´S Notes of Guidance for testing of cosmetic ingredients and their safety evaluation, 9th revision
- Commission implementing decision of Guidelines on Annex I to regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU)
- supplier`s specifications on raw materials
- http://www.specialchem4cosmetics.com
- http: //en.wikipedia.org
- http: //www.sigmaaldrich.com
- http://www.echa.europa.eu/web/guest/information-on-chemicals
- http://www.epa.gov
- http://oehha.ca.gov

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PART B – cosmetic product safety assessment

1. Assessment conclusion

In the common use of the cosmetic products according to the information enclosed for consumers and other available materials, no risk of irritation, sensitivity, local or systematic reactions to healthy people will occur.

From the point of view of the safety of human health and on the basis of the, aforesaid, the cosmetic product assessed can be assumed as safe for human health if their use stated in the instructions for consumers and the essential marking on the container of the cosmetic products are maintained according to European legislation valid on the date of issuance of this assessment

2. Labelled warnings and instruction of use

In accordance with article 19, there must be warnings stated on the label: ---

3. Reasoning

This assessment includes the conclusions of the total toxicological profile of the cosmetic product. The basic safety assessment feature observed is the identification of the dangerousness of the particular components of the cosmetic product, including their reciprocal interaction. The assessment is aimed at the risk (probability) of the creation of an undesirable effect (the method of application, the amount applied, the frequency of application, etc.). The risk is assessed on the basis of a synthesis of all the accessible data according to the current scientific knowledge referring to the determination of the type and degree of danger of the cosmetic substance or product. In relation to the particular components of the cosmetic product, the following undesirable effects are assessed: irritating, allergenic, mutagenic, teratogenic, carcinogenic and systematic (neurotoxic, hepatotoxic, nephrotoxic, hematotoxic, cardiotoxic and toxic effects for gastrointestinal and respiratory systems). Particularly in the case of leave-on products (permanent application – they are not washed-off), the possibility of health impairment after a long lasting effect of low concentrations of potentially toxic components is assessed.

4. Assessor´s credentials

This assessment relates only to the cosmetic products assessed; their composition, properties, information for customers and other materials essential for assessment (stated in point IV.) shall agree with the documents submitted for this assessment.

The evaluation of the functional properties of the product declared by the manufacturer is not part of this assessment.

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FICHA TÉCNICA

BARRO DEL MAR MUERTO

Product information:

Sample description: BARRO DEL MAR MUERTO
Gross weight (volume): 100 g
Date of consumption: PAO 12M
Batch code: 18032016

Information about Sampling:

Sampler: Customer

Microbiological tests

Parameter	Unit	Measured Value	Uncertainty*	Testing method /Process variance	SL	TT
Total viable count	CFU/g	<1x10¹	-	STN EN ISO 21149	NZ	A
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Yeast	CFU/g	<1x10¹	-	ČSN ISO 21527-2	NZ	N
Moulds	CFU/g	<1x10¹	-	ČSN ISO 21527-2	NZ	N
Escherichia coli	without/g	absent	-	STN 56 0100 čl.95	NZ	N
Staphylococcus aureus	-	absent	-	STN EN ISO 22718	NZ	A
Pseudomonas aeruginosa	-	absent	-	STN EN ISO 22717	NZ	A
Yeast genus Candida	-	absent	-	STN EN ISO 18416	NZ	A
Total anaerobic count at 20°C	CFU/g	<1x10¹	-	ŠPP MB.M.032	NZ	N

Physical and chemical tests

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Aluminium	mg/kg	17500	-	Varian Analytical Methods AES-ICP	TR	N
Arsenic	mg/kg	2,8	20%	LS-PP-CH-2/2	TR	A
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Copper	mg/kg	6,0	-	LS-PP-CH-2/8	TR	N
Iron	mg/kg	8310	-	Varian Analytical Methods AES-ICP	TR	N
Mercury	mg/kg	<0,01	-	LS-PP-CH-30	TR	A
Potassium	mg/kg	6480	-	LS-PP-CH-2/19 Methods AES-ICP	TR	N
Magnesium	mg/kg	26070	-	Varian Analytical Methods AES-ICP	TR	N
Manganese	mg/kg	206	-	Varian Analytical	TR	A
Sodium	mg/kg	18840	-	LS-PP-CH 2/18	TR	N
Nickel	mg/kg	42,4	-	LS-PP-CH-2/10	TR	N
Lead	mg/kg	<0,30	-	LS-PP-CH-2/25	TR	A
Antimony	mg/kg	0,033	-	LS-PP-CH-2/26	TR	N
Zinc	mg/kg	102	-	LS-PP-CH-2/12	TR	N

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Notes:

E - evaluation
S - satisfied
NS - not satisfied
ŠPP, LS-PP-CH - Standard operation procedure
ND - not detected by given method
CFU - Colony forming unit
NM - necessary quantity
m - the highest allowed value at the case of one sample
M, c - "M" highest allowed value for the number "c" at the case of 5 sample`s evaluation
* - uncertainty determined by extension coefficient k=2 (with probability of 95%) does not include the uncertainty of sampling.
- uncertainty given in units of analysed parameter reflects the uncertainty to the result of measurement.
- uncertainty given in % reflects the uncertainty from the result of measurement.
SL - analysing laboratory: BA-Bratislava, NZ-Nové Zámky, PN-Piešťany, TR-Turčianske Teplice, RK-Ružomberok, TV-Trebišov

TT - type of test
A - accredited test executed at the own test laboratory
N - non accredited test executed at the own test laboratory
SA - accredited test executed under the subcontract
SN - unaccredited test executed under the subcontract

Disclaimer:

Gauges and measuring equipment used for testing were calibrated or attested in accordance with the valid metrological instructions.
The above mentioned test results refer to the tested sample only!
The result given in this Test Certificate and marked as non accredited test shall not be a subject of accreditation.
The result given in this Test Certificate and marked as sub- delivery is the result of a Subcontractor's gauging made under the terms and conditions of a contract concluded eith him.
It´s not possible reproduce or incorporate the test certificate into promotional materials without laboratory written authorization!
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