

## TEST REPORT

Job No./Report No TR1942399

Date:3 August 2021

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### ZIYA ORGANIK TARIM ISLETMELERI A.Ş.

TURKOBA MAH. FIRAT PLASTIK CAD. NO:23 BUYUKCEKMECE/ISTANBUL

TEL: 0532 651 24 45

#### To the attention of Şefika OZCAN

The following sample(s) was (were) submitted and identified by/on behalf of the client as:

Sample No.	Sample Description
A	PELEMIR (CEPHALARIA SYRIACA L.) YAGI (OIL)

Client's reference No. : TR 1942399  
 Sample Receiving Date : 10 June 2021  
 Test Performing Period : 10 June 2021 ~ 3 August 2021

**Overall Conclusion** : **See Results**

Test Results : Please refer to the next page(s).

**Performed Test Summary:** Selected test(s) as requested by client against Client's performance standard.

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Test Parameters	Result
<b>Chemical tests</b>	<b>A</b>
Mesophilic Aerobic Plate Count	*
Yeasts & Moulds	*
<i>Candida Albicans</i>	*
<i>Pseudomonas Aeruginosa</i>	*
<i>Staphylococcus Aureus</i>	*
<i>Escherichia Coli</i>	*

Test Parameters	Result
<b>Dermatological tests</b>	<b>A</b>
Dermatological tests	*

Remarks	:	M = Meets client's requirement
		F = Exceed client's requirement
		I = Inconclusive
		* = No specified requirement
Notes:	Conclusions on meet/fail are based on the test result from the actual sampling of the received sample(s).	
	Residual sample can be returned to client if requested.	

The test results relate to the tested items only.  
Test reports without SGS seal and authorised signatures are invalid.

Issued in Istanbul  
Signed for and on behalf of  
SGS Supervise Gözetme Etüd Kontrol Servisleri A.Ş.

Mert Kurtuluş  
Customer Services Supervisor

Bora Şirinbilek  
Hardline & CPCH Testing Services Manager




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**Escherichia coli**
**Test Method :** With reference to TS EN ISO 21150:2015

<u>Tested Item</u>	<u>Result</u>	<u>Conclusion</u>	<u>Requirement</u>
<i>Escherichia coli</i>	<b>A</b> Not Detected	<b>See Results</b>	No Requirement

**Aerobic Mesophilic Bacteria**
**Test Method :** With reference to TS EN ISO 21149:2017

<u>Tested Item</u>	<u>Result (cfu/g)</u>	<u>Conclusion</u>	<u>Requirement</u>
Aerobic Mesophilic Bacteria	<b>A</b> <10	<b>See Results</b>	No Requirement

**Yeast and Mould**
**Test Method :** With reference to TS EN ISO 16212:2017

<u>Tested Item</u>	<u>Result (cfu/g)</u>	<u>Conclusion</u>	<u>Requirement</u>
Yeast and Mould	<b>A</b> <10	<b>See Results</b>	No Requirement

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**Staphylococcus aureus**
**Test Method :** With reference to TS EN ISO 22718:2015

<u>Tested Item</u>	<u>Result</u>	<u>Conclusion</u>	<u>Requirement</u>
<i>Staphylococcus aureus</i>	<b>A</b> Not Detected	<b>See Results</b>	No Requirement

**Pseudomonas aeruginosa**
**Test Method :** With reference to TS EN ISO 22717:2015

<u>Tested Item</u>	<u>Result</u>	<u>Conclusion</u>	<u>Requirement</u>
<i>Pseudomonas aeruginosa</i>	<b>A</b> Not Detected	<b>See Results</b>	No Requirement

**Candida albicans**
**Test Method :** With reference to TS EN ISO 18416:2015

<u>Tested Item</u>	<u>Result</u>	<u>Conclusion</u>	<u>Requirement</u>
<i>Candida albicans</i>	<b>A</b> Not Detected	<b>See Results</b>	No Requirement

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Information given by the Principal	Sample name:	1942399 - PELEMIR (CEPHALARIA SYRIACA L.) OIL
	Identification number given by Principal (series / production date / internal number):	134814/07/2021
	Product composition / INCI:	Yağ asitleri, E vitamini, 15-crown-5, Fitol.

Beginning of research:	05.07.2021
Completion of research:	15.07.2021
Comments on sample state / deviation:	NONE
Volunteers group:	25 volunteers
Skin type:	normal

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### 1. BASIS FOR RESEARCH IMPLEMENTATION

- Order form and test samples delivered by Principal
- Confirmation of microbiological purity / microbiological insensitivity

*The Principal is responsible for compliance with the declared quality composition of the samples sent for testing.*

### 2. PURPOSE OF RESEARCH

Product evaluation in terms of irritating and sensitizing properties.

### 3. LEGAL BASE OF RESEARCH

- Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of November 30, 2009, relating to cosmetic products.
- Cosmetics Europe- The Personal Care Association Guidelines „Product test Guidelines for the Assessment of Human Skin Compatibility 1997”.
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964 - 2013).
- The Act on Cosmetic Products, October 4, 2018, Journal of Laws No. 2018 item 2227.
- Test procedure by Skin Lab International Sp. z o.o.: PO-08 Research Implementation.
- Instruction by Skin Lab International Sp. z o.o.: I02/PO-08 Dermatological test – patch test.
- Instruction by Skin Lab International Sp. z o.o.: I04/PO-08 Scheme for assessing skin reactions - product classification.

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#### 4. VOLUNTEERS SELECTION

Volunteers participating in the research were selected on the basis of:

- Current European and Polish law
- Cosmetics Europe- The Personal Care Association
- Declaration of Helsinki (1964-2013)
- Test procedure by Skin Lab International Sp. z o.o.: PO-08 Research Implementation
- Instruction by Skin Lab International Sp. z o.o.: I01/PO-08 Volunteers qualification for the study

All volunteers selected for the study met the requirements for inclusion in the study and signed consent to voluntary participation in the study, and were informed about the purpose of the study, how it was conducted and about possible side effects. During the entire study, the volunteers were under the constant care of a dermatologist.

#### 5. METHODS OF RESEARCH

The test was performed in accordance with the research procedure of Skin Lab International Sp. z o.o. (PO-08 Research implementation) under the supervision of a dermatologist. The research model is the skin test according to Jadassohn-Bloch modified by Rudzki. The test consisted in a single application of the product to a selected area of the skin, and then observing the condition of the skin at intervals. The recording of the results and the classification of the product is made on the basis of the point classification (0-4) of the skin reaction (I04 / PO-08). Qualification, sample application and readings take place at Skin Lab International Sp. z o.o. in Cracow.

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**6. RESULTS**
**6.1. VOLUNTEERS IDENTIFICATION AND READINGS FROM THE TEST - POINT CLASSIFICATION**

VOLUNTER IDENTIFICATION NUMBER	SEX F - female M - male	AGE	RESULT			
			AFTER 48 h		AFTER 72 h	
			Erythema	Edema/ Swelling	Erythema	Edema/ Swelling
1	F	39	0	0	0	0
2	F	31	0	0	0	0
3	F	24	0	0	0	0
4	F	64	0	0	0	0
5	F	58	0	0	0	0
6	F	23	0	0	0	0
7	F	43	0	0	0	0
8	F	32	0	0	0	0
9	F	24	0	0	0	0
10	F	21	0	0	0	0
11	F	32	0	0	0	0
12	F	46	0	0	0	0
13	F	50	0	0	0	0
14	F	28	0	0	0	0
15	F	22	0	0	0	0
16	F	41	0	0	0	0
17	F	27	0	0	0	0
18	F	41	0	0	0	0
19	F	27	0	0	0	0
20	F	58	0	0	0	0
21	F	57	0	0	0	0
22	F	44	0	0	0	0
23	F	26	0	0	0	0
24	F	22	0	0	0	0
25	F	21	0	0	0	0

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## 6.2. IRRITATION INDEX ( $x_{ir}$ )

The average irritation index is calculated from the sum of the scores for erythema and edema. Based on the irritation index, the product is classified according to the scale.

AVERAGE IRRITATION INDEX ( $x_{ir}$ )	PRODUCT CLASSIFICATION
$x_{ir} < 0,5$	non-irritating
$0,5 < x_{ir} < 2,0$	slightly irritating
$2,0 < x_{ir} < 5,0$	moderately irritating
$5,0 \leq x_{ir}$	strongly irritating

Average irritation index for tested product:  $x_{ir} = 0$ , where  $x_{ir} = \frac{\text{sum of the scores}}{\text{volunteers number}}$

## 7. CONCLUSION

A dermatological study conducted on volunteers who were not allergic to any of the ingredients of the tested product confirms that the tested product is well tolerated by the skin, as it did not show any irritating or allergenic properties. The product can be classified as **NON-IRRITATING**.

**\*\* This test has been performed as subcontracted at SGS Polska.**



\* \* \* End of Test Report \* \* \*

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