

Laboratory Test Report

Report Number: R-5955-116-9950

Prepared for: Maelys Cosmetics Ltd

Customer Sample Description: B-Flat Firming Belly Cream

Eurofins Registration Number: 5955 / 2019-753-1399/1400

Test(s) Performed: In Use test under dermatological control with
instrumental evaluation

Date Received: 14/05/2019

Date(s) Tested: 30/05/2019 – 01/08/19

Results and Observations
Please refer to the following page(s)

Christine Dee
(Analytical Services Manager)

Date: 09/12/2019

The reported results relate exclusively to the tested sample.
The testing was performed by a laboratory within the Eurofins Group.

HUMAN IN USE TEST UNDER DERMATOLOGICAL CONTROL AND INSTRUMENTAL EVALUATION

Synopsis

STUDY OBJECTIVES	<p>This study intended:</p> <ul style="list-style-type: none"> - to check the skin acceptability - to assess the anti-cellulite efficacy by centimetric measurements and clinical scoring - to appreciate its cosmetic qualities and efficacy - to illustrate the efficacy on standardized photographs <p>in a panel of healthy human subjects after application under the normal conditions of use.</p>
SPONSOR	MAELYS COSMETICS LTD
STUDY MONITOR	Product Development Manager KEREN PELEG <i>email: keren@maelys.co.il</i>
INVESTIGATING CENTRE	EUROFINS EVIC PRODUCT TESTING ROMANIA S.R.L 64-66, Marasesti Avenue ; 040256 - Bucharest - Romania Tel.: +40 21 335 70 90 ; Fax: +40 21 335 70 91 <i>e-mail: evicromania@evic.ro</i>
MAIN INVESTIGATOR	Dr Rozalia Olsavszky (dermatologist) Registered N° (Romanian ministry of health): 461524 (specialist in dermatovenerology doctor, doctor in medical science) Tel: +40 21 335 70 90 Fax: +40 21 335 70 91 <i>e-mail: research@evic.ro</i>
CO-INVESTIGATORS	Dr Elena Chitoiu and Dr Monica Grigore (resident dermatologists) <i>e-mail: research@evic.ro</i>
TYPE OF THE STUDY	This monocentric study was performed in open
DATES OF STUDY PERFORMANCE	From 30/05/2019 to 01/08/2019
INVESTIGATIONAL PRODUCT	B-FLAT Firming Belly Cream

Synopsis (continuation)

<p style="text-align: center;">STUDY POPULATION</p>	<p>Number of test subjects: 20 valid cases.</p> <p>Specific inclusion criteria: test subjects</p> <ul style="list-style-type: none"> • aged from 25 to 40 • female • with a phototype (Fitzpatrick): II - IV • with all types of skin on body • having cellulite on abdomen with an individual clinical cellulite score (ICCS) from 1 to 3 (slight to very important cellulite state) according to the investigating center grading scale • having stretchmarks on abdomen • with body mass index < or= 30 <p>Specific non-inclusion criteria: test subjects</p> <ul style="list-style-type: none"> • with family or personal history of atopy • with anorexia • with body mass index > 30 • with varicose veins or evident capillaries • having treatment with slimming or anti-cellulite products stopped less than 3 months before the beginning of the study • with diet stopped less than 3 months before the beginning of the study • under anti-cellulite treatment: mesotherapy, electrotherapy, ionization, ultrasonotherapy, relaxation, acupuncture, hydrotherapy, lymphatic drainage, massage, sauna, ... • forecasting change in the way of life, physical activity or intensification of the usual physical activity • with circulatory insufficiency
<p style="text-align: center;">METHODOLOGY</p>	<p>Application of the investigational product:</p> <ul style="list-style-type: none"> • Application <u>at home</u> by the test subjects under normal conditions of use, under the following conditions: Application sites: abdomen Duration and frequency of use: 28 consecutive days+/- 2 days, twice a day. Investigational product directions for use: application of the product by massage in a circular motion until complete absorption. <p>Checking of the skin acceptability (local tolerance) based on:</p> <ul style="list-style-type: none"> • a skin examination of the abdomen by the same investigator or technician, supervised by investigator at the investigating centre: <ul style="list-style-type: none"> ▪ before product application (D1/T0) ▪ then after 28 consecutive days of product use (Dend±2 days) • the analysis of the sensations of discomfort reported directly by the test subjects to the investigator or to the technician, during the study or in the daily logs <p>Descriptive analysis - Percentage of reactive test subjects</p>

<p>METHODOLOGY (continuation)</p>	<p>The anti-cellulite efficacy based on:</p> <ul style="list-style-type: none"> • centimetric measurements on abdomen use by the technician <ul style="list-style-type: none"> ◦ before the product application (D1/T0), ◦ after 28 consecutive days of product (Dend±2 days) • clinical scoring of the cellulite on abdomen by the technician, supervised by investigator <ul style="list-style-type: none"> ◦ before the product application (D1/T0), ◦ after 28 consecutive days of product use (Dend±2 days) <p>Parameter of evaluation: Individual Centimetric Measurement and Individual Clinical Cellulite Score (ICCS)</p> <p>Illustration of product efficacy by standardized photographs <i>will be performed by technician:</i></p> <ul style="list-style-type: none"> · <i>on abdomen :</i> <ul style="list-style-type: none"> ◦ <i>front view with and without measuring tape</i> ◦ <i>one side view</i> · <i>on a chosen area with stretch marks (close picture)</i> <p>Appreciation of the cosmetic qualities and efficacy<i>after analysis of questionnaires adapted to the investigational product, elaborated with the study monitor and completed by each test subject, after 28 consecutive days +/- 2 days of use</i></p> <p><i>Parameter of evaluation: appreciation score - Percentage of satisfied test subjects</i></p>
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Synopsis (continuation)

RESULTS

Characteristics of the included panel

Number of included subjects: 20
 Number of exclusions: None
 Number of withdrawals: None
 Number of valid cases: 20

- Age: 31 to 40 (Mean: 35)
- Sex: female
- Phototype: II to IV
- Skin type on the application site: with all type of skin on body
- Having cellulite on abdomen with an individual clinical cellulite score (ICCS) from 1 to 3 (slight to very important cellulite state) according to the investigating center grading scale
- Having stretchmarks on abdomen: with mature stretch marks (100%; n = 20) and with immature stretch marks (30.00%; n=6)
- With body mass index < or= 30

Checking of the skin acceptability

No clinical signs imputable to the investigational product were observed by the investigator during the study.
 No sensations of discomfort were reported by the subjects during the study.

CLINICAL SIGNS (imputable to the investigational product)			
Reference of the concerned subjects	Description (Date - Type)	Test subjects	
		Nb	%
/	/	0	0%

Legend: / = none

SENSATIONS OF DISCOMFORT (imputable to the investigational product)			
Reference of the concerned subjects	Description (Date - Type)	Test subjects	
		Nb	%
/	/	0	0%

Legend: / = none

Assessment of the individual anti-cellulite effect on abdomen

The statistical analysis was done by the person in charge of the statistics using the software Spss version 22.0 for Windows.

All the test subjects included in the study were taken into account to assess the effect of the investigational product on the skin cellulite on abdomen, as long as they were submitted to the post application examinations at the defined times.

The statistical analysis was performed on the valid cases.

For the panel, the mean, standard deviation, median, minimum and maximum of the data were calculated, for each experimental time.

1. By centimetric measurements

Descriptive statistics

Statistics							
	N		Mean	Median	Std. Deviation	Minimum	Maximum
	Valid	Missing					
circumference_D1	20	0	95.90	96.50	6.23	84.00	104.00
circumference_Dend	20	0	95.30	96.00	5.85	85.00	103.00
circumference_Dend-D1	20	0	-.60	.00	1.23	-4.00	1.00

Comparisons of the data on D1 versus D29

		D1 versus Dend
N		20
Test		Paired t test
P		0.042
Statistical interpretation		S

S= significant (for $p < 0.05$)

NS = not significant (for $p \geq 0.05$)

Interpretation:

After 28 consecutive days of product use, the centimetric measurements of the abdomen varied statistically significant.

After 28 days of product use by a panel of 20 subjects, the centimetric values of the abdomen circumference registered an average decrease of 0.60 cm.

2. By clinical scoring (ICCS)

Descriptive statistics

Statistics							
	N		Mean	Median	Std. Deviation	Minimum	Maximum
	Valid	Missing					
ICCS_D1/T0	20	0	2.44	2.40	.43	1.40	3.00
ICCS_Dend	20	0	2.31	2.20	.46	1.40	3.00
ICCS_Dend-D1/T0	20	0	-.13	.00	.19	-.60	.00

Comparisons of the data on D1 versus D29

		D1 versus Dend
N		20
Test		Paired t test
P		0.006
Statistical interpretation		S

Interpretation:

After 28 days of product use, comparing to baseline, the individual clinical cellulite score (ICCS) for the abdomen had a decreasing trend, sustaining the anti-cellulite efficacy of the product on the treated area.

After 28 days of product use by a panel of 20 subjects, individual clinical cellulite score (ICCS) values for the abdomen registered an average decrease of 0.13 points.

Appreciation of the cosmetic qualities and efficacy after 28 days

See results below for:

1. General evaluation
2. Cosmetic qualities
3. Cosmetic efficacy
4. Future intentions

General evaluation

Items (20 valid cases)	Number of test subjects	Percentage of test subjects
I love it	17	85.00%
I like it	2	10.00%
I like it a little	0	0.00%
Not totally convinced	0	0.00%
Don't like it very much	1	5.00%
Don't like it at all	0	0.00%

Items	I love it	I like it	Don't like it very much
% of test subjects	85.00%	10.00%	5.00%

Cosmetic qualities

Items	The smell is pleasant	The color is good	The texture is nice	It is easily absorbed	The sense of heat is tolerable
% of satisfied test subjects	90.00%	95.00%	90.00%	90.00%	90.00%

Cosmetic efficacy

Items	Gives moisture and nourish the skin	Provides a firmer looking belly	Improves cellulite appearance	Minimize appearance of stretch marks	The cream brings results from the first week
% of satisfied test subjects	95.00%	90.00%	90.00%	85.00%	70.00%

Future intention for the product

Items	Will you intend continue using this product if you could?	Would you recommend this product to your friends?	At the end of this study would you like to buy this product (regardless of the price)?
% of test subjects	90.00%	90.00%	85.00%

OVERALL CONCLUSION

Under the experimental conditions adopted:

repeated application under normal conditions of use for 28 consecutive days, by a panel of 20 female test subjects, aged between 31 and 40 years old, with phototype II to IV, with all types of skin on body, with cellulite on abdomen and with individual clinical cellulite score (ICCS) on abdomen from 1 to 3, and with stretchmarks on abdomen,

the product **B-FLAT Firming Belly Cream** showed good skin acceptability.

The anti-cellulite efficacy of the product is sustained by the centimetric measurements and by the individual clinical cellulite scores (ICCS) on abdomen.

Globally, the product is well appreciated for its cosmetic qualities and efficacy.

Before and After Pictures- examples

