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microbiology - physicochemistry - sensory

GBA POLSKA Sp. z o.o.
Member of GBA GROUP
Headquarter address: ul. Mochtyńska 65, 03-289 Warsaw, Poland

TEST REPORT No.: K/0/10/2023/178/F/1/EN/P/1

Customer: MYTHOLOGY & ME,INC 92651 California, ul. 303 Broadway St.Laguna Beach

Order No.: K/0/10/2023/178

A - accredited methodology (AB 1095); reference – if the law so provides (the result can be used to assess compliance in the legally regulated area).
AE - accredited methodology (AB 1095) of flexible scope – reference if the law so provides / equivalent to reference (the result can be used to assess compliance in the legally regulated area).
AR - accredited methodology (AB 1095) equivalent to reference (the result can be used to assess compliance in the legally regulated area).
MON - methodology accredited in terms of "OiB"
GMP+ - methodology registered in the scope of GMP+ B11 protocol (feed testing)
A/P - accredited methodology of the subcontractor
P - non-accredited methodology of the subcontractor

Material/product tested:	**Cosmetics**			
Sample collection address:	35310 Güzelbahçe/ İzmir, ul. Yelki mah. 2245 sokak N:8IC KAPI N:2			
Product name:	**MYTHOLOGY & ME ARTEMIS ECZEMA CREAM**			**Date*: 10.10.2023**
Producer:	own production			
Date of production:	20/09/2023			
Lot number:	50 ML	20.09.2023	20.09.2025	2309005-MM02
Notes on the sample:	lack			

Samples collected according to: samples taken by the Customer
Samples transported by: Shipping
Sample receiver: GBA POLSKA employee no.: 2744

Sample no.: 15488/10/23 Sample evaluation: unreservedly Analysis start date: 23-10-2023 Analysis end date: 23-11-2023

Lab.	Analyzed parameter	Unit	Accred.	Test method	Requirement	Result	MU**	N
	HRIPT test.		P	Own method	no requirements	in Attachment		

Date* - depending on the method of obtaining the sample by GBA Polska, it is the date of: collection (when the sample is collected only by a GBA Polska employee) or collection (when the sample is collected from customer by a GBA Polska employee, is delivered by a courier company or delivered personally by the customer).
** - expanded measurement uncertainty at the level of confidence app. 95% and the coverage factor k=2, does not take into account the sampling uncertainty, except when indicated in the remarks.
Measurement uncertainty is presented when: it is relevant to the validity or application of the test results, it affects conformity to a specification limit, or a customer's instruction so requires.
The test results lower or higher than the measuring ranges of the methods are presented as "<value of the lower limit of the measuring range " or "> value of the upper limit of the measuring range", respectively. If expanded uncertainties are given with these test results, they apply to the lower or upper limit of the measuring range of the method. Moreover, in the case of these results, the conformity statement should be treated as an opinion and interpretation. The above-described procedure does not apply to biological tests.
The results relate to the tested samples (sampled or received - as reported in the test report).
In the case of samples provided by the customer, the information presented in the report regarding these samples is the information provided by the customer. The Laboratory is not responsible for this information or for the method of sampling and the representativeness of the samples provided by the customer for testing.
The test report includes test results of the following number of samples: 1 pc(s) and without the written approval of the Laboratory shall not be reproduced except in full.
Customer may file complains within 14 days from receiving the report.
The Laboratory does not store the samples after testing, unless otherwise agreed with the customer.
Place of performance of the tests (location codes): Ł - Łajski, L - Lublin, M - Mysłowice, PS - in situ measurement.

Remarks:
* Subcontracted, non-accredited tests were performed at the Specialist Application Dermatology Office-Dabawczy Marek Brzewski, Paweł Brzewski SC

NOTE: The original test reports are issued as PDF file, signed with a qualified electronic signature. Therefore, all prints are copies, unless certified to be true to the original PDF file.

Report prepared in a single copy **The end of the Report** **Original of PDF: Customer, copy of PDF to: Laboratory archive**

Created on:	Authorized by:	Approved by:	
07-12-2023	GBA POLSKA employee no.: 2566	GBA POLSKA employee no.: 2550	ANNA SOT Elektronicznie podpisany przez ANNA SOT Data: 2023.12.07 13:14:55 +01'00' **Signed with a qualified electronic signature**

Specjalistyczny Gabinet Dermatologiczny
Aplikacyjno- Badawczy
Marek Brzewski, Paweł Brzewski S.C.
Ul. Zbożowa 2/25, 30-002 Kraków, Poland
NIP: 676 248 41 46
tel.: +48 600 244 514
info@dermatolog-brzewski.com

Kraków, 2023-11-24 P/754/01/2023

FINAL REPORT

SENSITIZING POTENTIAL STUDY OF A COSMETIC PRODUCT ACCORDING TO MARZULLI-MAIBACH METHOD

HRIPT- FINAL CLINICAL SECURITY TEST

MYTHOLOGY & ME ARTEMIS ECZEMA CREAM

Ordered by: GBA POLSKA Sp. z o.o.

Łajski, Kościelna 2a

05-119 Legionowo, Poland

Study of initiation date: 23.10.2023

Completion date of test: 23.11.2023

Signature Not Verified

Dokument podpisany przez
Paweł Łukasz Brzewski
Data: 2023.11.30 22:56:04 CET

STUDY SUMMARY

TITLE: MYTHOLOGY & ME ARTEMIS ECZEMA CREAM DURING 4 WEEKS- FINAL CLINICAL SECURITY TEST

PRODUCT: MYTHOLOGY & ME ARTEMIS ECZEMA CREAM

STUDY IMPLEMENTATION: The study was carried out and all test recorded by the Specjalistyczny Gabinet Dermatologiczny Marek Brzewski, Paweł Brzewski s.c.; Zbożowa 2/25 St., 30-002 Kraków, POLAND

INVESTIGATOR: MD, PhD Paweł Brzewski

PROTOCOL: Clinical evaluation of the sensitizing potential of a product according to Marzulli- Maibach Method.

AIM OF THE STUDY: Evaluate the sensitizing potential of a product under dermatological control and under the conditions defined by study's sponsor.

SUBJECT: 20 healthy subjects with normal or sensitive skin corresponding to the inclusion and non-inclusion criteria.

STUDY SCHEDULE: 23rd October, 2023 to 23rd November, 2023

MAIN TOLERANCE PARAMETERS:

- Irritation potential (Induction Phase)
  Erythema, edema, desquamation, vesicles rated from 0 to 3 by the dermatologist
- Sensitizing potential (Challenge Phase)
  Reaction rated from 0 to 3 by the dermatologist according to ICDRG (International Contact Dermatitis Research Group)

RESULTS:

Product RW	Irritation potential	Sensitizing potential
MYTHOLOGY & ME ARTEMIS ECZEMA CREAM	Mean rate of 0,000= **non irritating**	No allergic reaction

CONCLUSION: Under these study conditions, product: MYTHOLOGY & ME ARTEMIS ECZEMA CREAM can be considered as **non-irritating** and **non-sensitizing.**

1. QUALITY POLICY

The study described has been conducted according to the TCSF-AFFSAPS recommendations (December 2008 final version) and the most recent recommendations of the world medical association (Helsinki 1964 declaration in its current version) and to the Good Clinical Practice Guidelines from FDA (FR of 8/08/1978 Part V- Decree n°77N-0278) and to the Ministry of Health of the Polish Republic.

The Study has been conducted according to Standard Operating Procedures and to the study protocol defined by the sponsor. Every study events recorded during the study is reported.

The first evaluation of sensitization risks for all ingredients depends on the responsibility of the tested product manufacturer.

Controls on data veracity and conformity with the protocol, have been performed and confirmed by persons participating to the study.

2. CONFORMITY CERTIFICATE

I am aware that the study has been conducted according to the **QUALITY POLICY** described before.

There was no event which may have affected the quality or integrity of the data.

Dr n. med. PAWEŁ BRZEWSKI
SPECJALISTA
DERMATOLOG-WENEROLOG
tel. 600-244-5[illegible]4 2293825

_____ 24th November, 2023

MD, PhD Paweł Brzewski

3. METHOD

3.1 STUDY PRODUCT

The product delivered by GBA POLSKA Sp. z o.o. has the following characteristics:

Name of the product	Product presentation	Study ref
MYTHOLOGY & ME ARTEMIS ECZEMA CREAM	cream	RW
Ingredients INCI		
AQUA, GLYCERIN, PROPANEDIOL, CHLAMYDOMONAS ACIDOPHILA EXTRACT, HYPERICUM PERFORATUM OIL, SODIUM LEVULINATE, BOSWELLA SERRATA OIL, POGOSTEMON CABLIN LEAF OIL, PELARGONIUM GRAVEOLENS OIL, HELICHRYSUM ITALICUM FLOWER/LEAF/STEM OIL, SALVIA SCLAREA OIL, ACACIA SENEGAL GUM, XANTHAN GUM, POTASSIUM SORBATE, CITRIC ACID.		

3.2 AIM OF THE STUDY

Test have to assess the irritating potential and sensitizing potential of the product under dermatological control and according to the Marzulli-Maibach method.

3.3 STUDY SUBJECTS

Inclusion criteria:

- Healthy subjects of Caucasian origin, male or female,
- Age between 19 and 59,
- Phototype II, III or IV,
- Sensitive skin

Non-inclusion criteria:

- Pregnancy or nursing women,
- Sun exposure or UV exposure 15 days before study and/or photopatch from less than 2 months,
- Hyper irritable skin,
- Known allergies or sensitivities to cosmetics product,
- Skin pathology on the test zones, scars, beauty spots, freckle or any abnormality, on the back,
- Subjects afflicted with serious or progressive diseases,
- Subjects undergoing a topical or systemic treatment: anti- inflammatories, antihistamines, immune-suppressors, corticoids and retinoids.

4. PRODUCT APPLICATION

Application area: Scapular zones: homolateral (induction zone) and contralateral (challenge zone)

Frequency & Contact time:

Induction Phase: 3 times a week during 48 hours

Challenge Phase: once during 48 hours

Phase duration:

Induction Phase: 2 weeks

Rest Phase: 1 week

Challenge Phase: 1 week

Application conditions:

Before any application, skin was cleaned and dried. The product was applied like an occlusive patch to the subject's back. During all induction phase, the homolateral zone was not wet. The subjects take a shower on Sunday, after patches removing and pay attention to not put a detergent product on all tested zones. During all Challenge Phase, any of washing or other products do not take place on contralateral zone.

5. STUDY SCHEDULE

The study was carried out according to the following schedule:

Induction Phase:

Week 1:

Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
Study day	D1	D2	D3	D4	D5	D6	D7
Product application	Ɵ		Ɵ		Ɵ		
Reading			Ṛ		Ṛ		

Week 2:

Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
Study day	D8	D9	D10	D11	D12	D13	D14
Product application	ʘ		ʘ		ʘ		
Reading	Ṛ		Ṛ		Ṛ		

After removing the last patch, the subject was asked to come at the clinical unit on day 15 if any new signs appeared (or deterioration of any an existing sign D12).

Rest Phase:

Week 1:

Day of the week	Mo	Tu	We	Th	Fr	Sa	Su
Study day	D15	D16	D17	D18	D19	D20	D21

Challenge Phase:

Week 1:

Day of the week	Mo	Tu	We	Th	Fr
Study day	D22	D23	D24	D25	D26
Product application	ʘ				
Reading			Ṛ		Ṛ

6. ASSESSMENT CRITERIA

6.1 CLINICAL CRITERIA REGARDING THE IRRITATING POTENTIAL (INDUCTION PHASE)

After each application, the patch was removed and the clinical examination was performed by the investigator 30 minutes later in order to eliminate the pressure and the occlusion effects.

The results of the examination was zero if the skin looked normal.

The clinical examination is made on the back using the following criteria and scale:

Score	Quotation	CRITERIA: description			
		ERYTHEMA	EDEMA	DRYNESS	VESICLES
0	Absent	Normal aspect	Normal aspect	Normal aspect	Normal aspect
1	Slight	Discreet pink coloration of the whole tested area or rather visible on part of the tested area	More palpable than visible edema	Discreet thin desquamation, tarnished aspect	More palpable than visible vesicles
2	Marked	Marked erythema covering the whole tested area	Visible edema	Visible desquamation, flaky aspect	Visible vesicles
3	Important	Severe erythema covering the whole tested area or erythema diffusing beyond the tested area	Edema diffusing beyond the tested area	Important desquamation, cracking	Vesicles diffusing beyond the tested area or blisters

6.2 CLINICAL CRITERIA REGARDING THE SENSITIZING POTENTIAL (CHALLENGE PHASE)

The allergic reactions are evaluated to the following scale:

Criteria	Quotation ICDRG (International Contact Dermatitis Research Group)	Score noted in all tables
No reaction	0	0
Doubtful reaction	?	?
Erythema and edema	+	1
Erythema, edema and vesicles	++	2
Severe reaction with blisters	+++	3

6.3 ASSESSMENT METHOD

IRRITATING POTENTIAL- INDUCTION PHASE

The average results of every volunteer was calculating by adding the results obtained for each of the readings and by dividing this sum by the actual number of readings made at the clinical unit (reading was not taken into account if there was a reaction of the control or global irritation).

The irritating potential (IRR) is determined according the following formula:

$$I.R.R = \frac{[(\sum scoresD1 \dots D12 \,/\, nb\ of\ regardings)vol1 \dots + (\sum scoresD1 \dots D12 \,/\, nb\ of\ regardings)volN]}{nb\ of\ subjects\ (N)}$$

Average score (IRR)	Irritating Potential
score <0,080	non-irritating
0,080 ≤ score < 0,160	very slightly irritating
0,160 ≤ score < 0,560	slightly irritating
0,560 ≤ score < 1,000	moderaty irritating
1,000 ≤ score < 1,600	strongly irritating
1,600 ≤ score	very strongly irritating

SENSITIZING POTENTIAL- CHALLENGE PHASE

The possible allergic reaction, during the Induction or Challenge Phase, will be rated from 0 to 3 according to ICDRG (International Contact Dermatitis Research Group). During the Challenge Phase, the reading will take place 30 minutes after patch removal and 48 hours later D24 and D26.

The sensitizing potential of the product will be assessed by the reading D24 and D26 (Challenge Phase) as a function of the following criteria: reaction ++ (2) or +++ (3) in the absence of added irritation phenomenon.

The presence of only one case of active sensitizing (upper or equal results in ++ (2)) on contralateral side leads to the conclusion “Potentially sensitive product”.

6.4 PREMATURE STUDY TERMINATION

The subjects have the right to leave the study any time, whatever the reason. The premature study termination can be for multiple reasons:

- Non- compliance with the visits schedule by the subject,
- Adverse events (including intercurrent diseases)
- Protocol non-adherence/ departures from protocol,
- Withdrawal of subject’s consent.

The doctor investigator can interrupt the essay either on certain subjects or on the whole panel, in the product induces important or abnormal cutaneous reactions or if he considers that the continuation of the essay can damage of one or several concerned subjects.

7. RESULTS

7.1 IRRITATING POTENTIAL- INDUCTION PHASE

The TABLE OF READINGS regarding the Induction Phase is presented in ATTACHMENT III.

These reading was made 30 minutes after having removed the patch-tests, showed the following results:

Product RW	D3	D5	D8	D10	D12	Conclusion
MYTHOLOGY & ME ARTEMIS ECZEMA CREAM	Results- number of subjects					**non-irritating** IRR=0,000
	T+ :0 0: 50	T+ :0 0: 50	T+ :0 0: 50	T+ :0 0: 50	T+ :0 0: 50	
	Results- Percentage					
	T+ :0 0: 100%	T+ :0 0: 100%	T+ :0 0: 100%	T+ :0 0: 100%	T+ :0 0: 100%	

Under these study conditions, product: **MYTHOLOGY & ME ARTEMIS ECZEMA CREAM** showed a results lower than 0,080, so it can be considered as **NON-IRRITATING**.

7.2 SENSITIZING POTENTIAL: CHALLENGE PHASE

The TABLE OF READINGS regarding the Challenge Phase is presented in ATTACHMENT IV.

These reading was made 30 minutes and 48 hours after having removed the patch-tests, showed the following results:

Product Code RW	Zones	Score	Days of reading				Global result
			D24		D26		
			n	%	n	%	
MYTHOLOGY & ME ARTEMIS ECZEMA CREAM	Homolateral zone	T+:	0	0	0	0	non-sensitizing
		0:	50	100	50	100	
		?:	0	0	0	0	
		1:	0	0	0	0	
		2:	0	0	0	0	
		3:	0	0	0	0	
	Controlateral zone	T+:	0	0	0	0	
		0:	50	100	50	100	
		?:	0	0	0	0	
		1:	0	0	0	0	
		2:	0	0	0	0	
		3:	0	0	0	0	

T+= positive control

VM= missing value

N= number of subjects

%= % of subjects

Under these conditions, no reaction ++ (2) or +++ (3) were observed, so the product MYTHOLOGY & ME ARTEMIS ECZEMA CREAM can be considered as **non-sensitizing.**

8. CONCLUSION

Under these study conditions, the product MYTHOLOGY & ME ARTEMIS ECZEMA CREAM can be considered non-irritating and non-sensitizing.

ATTACHEMENTS

ATTACHMENT I:

RESULTS AUTHENTIFICATION SHEET

ATTACHMENT II:

SUBJECT CHARACTERISTICS

ATTACHMENT III:

TABLE OF READING- INDUCTION PHASE

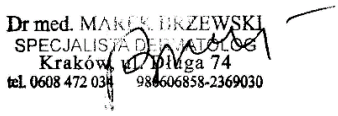
ATTACHMENT I

RESULTS AUTHENTIFICATION SHEET

AUTHENTIFICATION PAGE

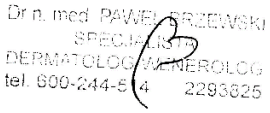
I am aware that the study N°: P/754/01/2023

Has been conducted according to the PROTOCOL and to the STUDY PARAMETERS PAGE.



MD, PhD Marek Brzewski

Dermatologist *signature*



MD, PhD Paweł Brzewski

Dermatologist *signature*

ATTACHMENT II

SUBJECT CHARACTERISTICS

Subject number	Age	Sex F or M	Phototype	Skin type (**N**ormal or **S**ensivite)	Medical or surgical events and medical treatments	
					before the study	before the study
1	35	F	II	N	-	-
2	51	F	II	S	-	-
3	56	F	II	S	-	-
4	43	F	II	S	-	-
5	52	F	II	N	-	-
6	36	F	II	N	-	-
7	52	F	II	N	-	-
8	51	M	II	N	-	-
9	34	M	III	N	-	-
10	59	F	II	S	-	-
11	35	F	II	S	-	-
12	39	F	IV	N	-	-
13	57	F	II	N	-	-
14	36	M	II	N	-	-
15	26	F	III	N	-	-
16	43	F	II	N	-	-
17	42	F	II	N	-	-
18	52	M	II	N	-	-
19	32	F	II	N	-	-
20	59	F	II	N	-	-

ATTACHMENT III

TABLE OF READING

INDUCTION PHASE

Subject number	D3	D5	D8	D10	D12
	C	RW	C	RW	C
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
5	0	0	0	0	0
6	0	0	0	0	0
7	0	0	0	0	0
8	0	0	0	0	0
9	0	0	0	0	0
10	0	0	0	0	0
11	0	0	0	0	0
12	0	0	0	0	0
13	0	0	0	0	0
14	0	0	0	0	0
15	0	0	0	0	0
16	0	0	0	0	0
17	0	0	0	0	0
18	0	0	0	0	0
19	0	0	0	0	0
20	0	0	0	0	0

ATTACHMENT IV

TABLE OF READING

CHALLENGE PHASE

Subject number	D24 Homolateral zone		D26 Controlateral zone		D24 Homolateral zone		D26 Controlateral zone	
	C	RW	C	RW	C	RW	C	RW
1	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0