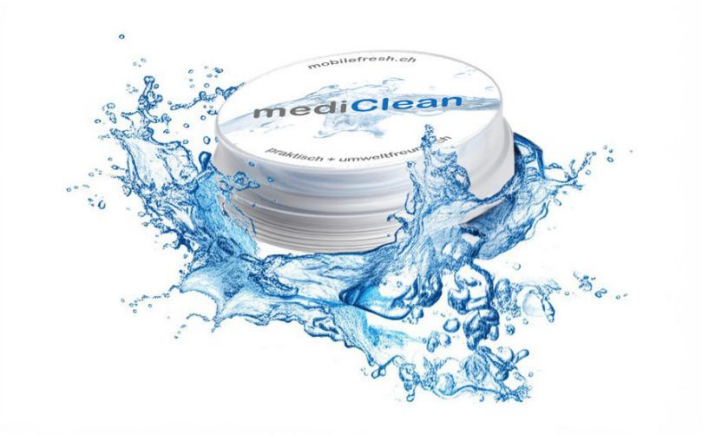

Sicherheits- & Qualitätsnachweis mediClean (PDF)

(Stabilitätsdaten, Hautverträglichkeit, mikrobiologische und chemische Sicherheit)

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QUALITY ASSURANCE & CONTROL SYSTEMS
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TEST REPORT 22 26 00027

STABILITY TEST REPORT

9 MONTHS PROTOCOL

MEDI CLEAN

MOBILEFRESH AG

DECEMBER 2022

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PRODUCT DESCRIPTION

The product 'MEDI CLEAN' is a pop-up towel (leave one product), of white color and characteristic odor that is kept in a plastic container.

TEST PRODUCT DESCRIPTION

PRODUCT MANUFACTURED BY	: **MOBILEFRESH AG**
RECEIPT DATE	: **28/02/2022**
STUDY PERIOD	: **28/02/2022 - 07/11/2022**
LAB ID	: **22 26 00027**
TEST PRODUCT	: **MEDI CLEAN**
PRODUCT TYPE	: **POP-UP TOWEL**
LOT	: **V1.0**
STUDY SPONSOR	: **MOBILEFRESH AG**

OBJECTIVE

The objective of stability testing is to ensure that the cosmetic product maintains its intended physical, chemical and microbiological quality and properties, as well as its functionality and aesthetics when stored under appropriate conditions. Main scope is to provide data by foreseeing the stability of the product overtime within its useful life span and the compatibility between the formulation and the container material.

METHOD DESIGN

The method was designed to include testing of the properties of the cosmetic product that are susceptible to change during storage and are likely to influence quality, safety, and performance characteristics. The testing covers the sensorial, physical, chemical, and microbiological attributes, the preservation system and its efficacy. Analytical procedures are performed in accordance with standard protocols. For the measurable attributes, a ± 20 % variation from the initial assay value (time zero) is set as the action limit. A stable product should meet standard requirements for sensorial, physical and microbiological properties. A sample stored at room temperature is considered as reference for sensorial properties.

REFERENCES

- ISO-9001: 2015
- ICH Q 1 A (R2)
- EC 1223/2009
- COLIPA Guide on stability testing of cosmetic products, 2004
- IFSCC Monograph No2 The Fundamentals of Stability Testing

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PROTOCOL

The stability study includes the evaluation of the below attributes at specific storage conditions and time intervals.

- ✓ Organoleptic: appearance, color, odor and texture
- ✓ Physical-chemical: pH, assay of preservatives
- ✓ Compatibility between product and container

STABILITY ROOM TEMPERATURE (RT, 25 °C)

The samples are stored at room temperature (25°C ± 2°C). At the beginning of the stability (week 0) all parameters are evaluated (time zero). Organoleptic – physicochemical controls are carried out weekly. Upon conclusion of the study (9 months) all parameters are reexamined.

STABILITY ACCELERATED (40 °C / 75% RH)

The samples are stored in a chamber (40 °C ± 2 / 75% RH ± 5). Compatibility between the formulation and the container material is monitored on a weekly basis. Upon conclusion of the study (9 months) all the above parameters are reevaluated.

STABILITY REFRIGERATOR (5 °C)

The samples are stored in a refrigerator (5°C ± 2°C). Organoleptic – physicochemical controls are carried out weekly. Upon conclusion of the study (9 months) physicochemical parameters are also reexamined.

STABILITY CYCLES

The samples are stored in a freezer (-20°C ± 2°C) for eight hours and permitted to thaw at room temperature. The organoleptic and sensorial attributes are evaluated. The same samples are left at room temperature (25°C ± 2°C) for 16 hours and then reevaluated. The study is completed after five -5- days, during which a total of 5 freeze – thaw cycles are completed.

STABILITY DARK & WINDOW

Samples are kept in a closed cabinet (dark) and nearby a window (diffused light). Organoleptic sensorial attributes, are evaluated weekly. The study is completed within nine months.

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STABILITY TEST SCHEDULE AND PLANNING

The test schedule of the product has been adjusted according to its nature and formula.

The time schedule below describes the time intervals at which samples stored at different conditions are tested and what tests are applied at each examination.

Time (Weeks)	5 ^{0}C	25 ^{0}C	40 ^{0}C	Dark-Window	-20 ^{0}C 8h-+25 ^{0}C 16h
0	P	P	PX	P	P
1	P	P	P	P	P
2	P	P	P	P	-
3	P	P	P	P	-
4	P	P	P	P	-
5	P	P	P	P	-
6	P	P	P	P	-
7	P	P	P	P	-
8	P	P	P	P	-
9	P	P	P	P	-
10	P	P	P	P	-
11	P	P	P	P	-
12	P	P	P	P	-
13	P	P	P	P	-
14	P	P	P	P	-
15	P	P	P	P	-
16	P	P	P	P	-
17	P	P	P	P	-
18	P	P	P	P	-
19	P	P	P	P	-
20	P	P	P	P	-
21	P	P	P	P	-
22	P	P	P	P	-
23	P	P	P	P	-
24	P	P	P	P	-
25	P	P	P	P	-
26	P	P	P	P	-
27	P	P	P	P	-
28	P	P	P	P	-
29	P	P	P	P	-
30	P	P	P	P	-
31	P	P	P	P	-
32	P	P	P	P	-
33	P	P	P	P	-
34	P	P	P	P	-
35	P	P	P	P	-
36	P	P	PX	P	-

Where:

P= Appearance, Odor, Texture, Color, pH, Packaging Compatibility

C= Preservative challenge tests

X= Assay of preservatives

- : Not tested

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RAW DATA

Customer	**MOBILEFRESH AG**
Product	**MEDI CLEAN**
Conditions	**25 °C**
Lab ID	**22 26 00027**
Manufacture batch	**V1.0**
Manufacture date	**N/A**
Stability Start date	**28/02/2022**

TEMPERATURE	DATE	WEEKS	APPEARANCE	ODOR	COLOR	TEXTURE	CONTAINER	pH
25° C	28/02/2022	0	OK	OK	OK	OK	OK	6,39
	07/03/2022	1	OK	OK	OK	OK	OK	6,62
	14/03/2022	2	OK	OK	OK	OK	OK	6,29
	21/03/2022	3	OK	OK	OK	OK	OK	6,22
	28/03/2022	4	OK	OK	OK	OK	OK	6,30
	04/04/2022	5	OK	OK	OK	OK	OK	6,33
	11/04/2022	6	OK	OK	OK	OK	OK	6,35
	18/04/2022	7	OK	OK	OK	OK	OK	6,35
	25/04/2022	8	OK	OK	OK	OK	OK	5,35
	02/05/2022	9	OK	OK	OK	OK	OK	6,36
	09/05/2022	10	OK	OK	OK	OK	OK	6,36
	16/05/2022	11	OK	OK	OK	OK	OK	6,37
	23/05/2022	12	OK	OK	OK	OK	OK	6,37
	30/05/2022	13	OK	OK	OK	OK	OK	6,37
	06/06/2022	14	OK	OK	OK	OK	OK	6,34
	13/06/2022	15	OK	OK	OK	OK	OK	6,34
	20/06/2022	16	OK	OK	OK	OK	OK	6,36
	27/06/2022	17	OK	OK	OK	OK	OK	6,36
	04/07/2022	18	OK	OK	OK	OK	OK	6,40
	11/07/2022	19	OK	OK	OK	OK	OK	6,41
	18/07/2022	20	OK	OK	OK	OK	OK	6,42
	25/07/2022	21	OK	OK	OK	OK	OK	6,42
	01/08/2022	22	OK	OK	OK	OK	OK	6,43
	8/08/2022	23	OK	OK	OK	OK	OK	6,45

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	15/08/2022	24	OK	OK	OK	OK	OK	6,46
	22/08/2022	25	OK	OK	OK	OK	OK	6,46
	29/08/2022	26	OK	OK	OK	OK	OK	6,47
	05/09/2022	27	OK	OK	OK	OK	OK	6,47
	12/09/2022	28	OK	OK	OK	OK	OK	6,48
	19/09/2022	29	OK	OK	OK	OK	OK	6,48
	26/09/2022	30	OK	OK	OK	OK	OK	6,49
	03/10/2022	31	OK	OK	OK	OK	OK	6,49
	10/10/2022	32	OK	OK	OK	OK	OK	6,49
	17/10/2022	33	OK	OK	OK	OK	OK	6,50
	24/10/2022	34	OK	OK	OK	OK	OK	6,50
	31/10/2022	35	OK	OK	OK	OK	OK	6,51
	07/11/2022	36	OK	OK	OK	OK	OK	6,51
Variation from initial value %								1,9
Conclusion								Pass

- : Not tested

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Customer	**MOBILEFRESH AG**
Product	**MEDI CLEAN**
Conditions	**25 °C**
Lab ID	**22 26 00027**
Manufacture batch	**V1.0**
Manufacture date	**N/A**
Stability Start date	**28/02/2022**

Parameter	Result (%)		Variation from initial value (%)
	Week 0	Week 12	
Methyl Paraben	0,14	0,13	-7,1

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	MOBILEFRESH AG
Product	**MEDI CLEAN**
Conditions	**40 °C, 75% RH**
Lab ID	**22 26 00027**
Manufacture batch	**V1.0**
Manufacture date	**N/A**
Stability Start date	**28/02/2022**

TEMPERATURE	DATE	WEEKS	APPEARANCE	ODOR	COLOR	TEXTURE	CONTAINER	pH
40° C / 75 %RH	28/02/2022	0	OK	OK	OK	OK	OK	6,40
	07/03/2022	1	OK	OK	OK	OK	OK	6,63
	14/03/2022	2	OK	OK	OK	OK	OK	6,34
	21/03/2022	3	OK	OK	OK	OK	OK	6,30
	28/03/2022	4	OK	OK	OK	OK	OK	6,30
	04/04/2022	5	OK	OK	OK	OK	OK	6,32
	11/04/2022	6	OK	OK	OK	OK	OK	6,33
	18/04/2022	7	OK	OK	OK	OK	OK	6,33
	25/04/2022	8	OK	OK	OK	OK	OK	6,34
	02/05/2022	9	OK	OK	OK	OK	OK	6,34
	09/05/2022	10	OK	OK	OK	OK	OK	6,34
	16/05/2022	11	OK	OK	OK	OK	OK	6,34
	23/05/2022	12	OK	OK	OK	OK	OK	6,34
	30/05/2022	13	OK	OK	OK	OK	OK	6,35
	06/06/2022	14	OK	OK	OK	OK	OK	6,33
	13/06/2022	15	OK	OK	OK	OK	OK	6,33
	20/06/2022	16	OK	OK	OK	OK	OK	6,34
	27/06/2022	17	OK	OK	OK	OK	OK	6,34
	04/07/2022	18	OK	OK	OK	OK	OK	6,40
	11/07/2022	19	OK	OK	OK	OK	OK	6,41
	18/07/2022	20	OK	OK	OK	OK	OK	6,41
	25/07/2022	21	OK	OK	OK	OK	OK	6,42
	01/08/2022	22	OK	OK	OK	OK	OK	6,43
	8/08/2022	23	OK	OK	OK	OK	OK	6,49
	15/08/2022	24	OK	OK	OK	OK	OK	6,50

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	22/08/2022	25	OK	OK	OK	OK	OK	6,50
	29/08/2022	26	OK	OK	OK	OK	OK	6,51
	05/09/2022	27	OK	OK	OK	OK	OK	6,51
	12/09/2022	28	OK	OK	OK	OK	OK	6,52
	19/09/2022	29	OK	OK	OK	OK	OK	6,52
	26/09/2022	30	OK	OK	OK	OK	OK	6,53
	03/10/2022	31	OK	OK	OK	OK	OK	6,53
	10/10/2022	32	OK	OK	OK	OK	OK	6,53
	17/10/2022	33	OK	OK	OK	OK	OK	6,54
	24/10/2022	34	OK	OK	OK	OK	OK	6,54
	31/10/2022	35	OK	OK	OK	OK	OK	6,55
	07/11/2022	36	OK	OK	OK	OK	OK	6,55
Variation from initial value %								2,3
Conclusion								Pass

- : Not tested

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Customer	**MOBILEFRESH AG**
Product	**MEDI CLEAN**
Conditions	**5 °C**
Lab ID	**22 26 00027**
Manufacture batch	**V1.0**
Manufacture date	**N/A**
Stability Start date	**28/02/2022**

TEMPERATURE	DATE	WEEKS	APPEARANCE	ODOR	COLOR	TEXTURE	CONTAINER	pH
5° C	28/02/2022	0	OK	OK	OK	OK	OK	6,40
	07/03/2022	1	OK	OK	OK	OK	OK	6,60
	14/03/2022	2	OK	OK	OK	OK	OK	6,28
	21/03/2022	3	OK	OK	OK	OK	OK	6,25
	28/03/2022	4	OK	OK	OK	OK	OK	6,28
	04/04/2022	5	OK	OK	OK	OK	OK	6,30
	11/04/2022	6	OK	OK	OK	OK	OK	6,32
	18/04/2022	7	OK	OK	OK	OK	OK	6,32
	25/04/2022	8	OK	OK	OK	OK	OK	6,33
	02/05/2022	9	OK	OK	OK	OK	OK	6,33
	09/05/2022	10	OK	OK	OK	OK	OK	6,34
	16/05/2022	11	OK	OK	OK	OK	OK	6,34
	23/05/2022	12	OK	OK	OK	OK	OK	6,35
	30/05/2022	13	OK	OK	OK	OK	OK	6,35
	06/06/2022	14	OK	OK	OK	OK	OK	6,33
	13/06/2022	15	OK	OK	OK	OK	OK	6,33
	20/06/2022	16	OK	OK	OK	OK	OK	6,36
	27/06/2022	17	OK	OK	OK	OK	OK	6,36
	04/07/2022	18	OK	OK	OK	OK	OK	6,39
	11/07/2022	19	OK	OK	OK	OK	OK	6,40
	18/07/2022	20	OK	OK	OK	OK	OK	6,41
	25/07/2022	21	OK	OK	OK	OK	OK	6,41
	01/08/2022	22	OK	OK	OK	OK	OK	6,42
	8/08/2022	23	OK	OK	OK	OK	OK	6,43
	15/08/2022	24	OK	OK	OK	OK	OK	6,43

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	22/08/2022	25	OK	OK	OK	OK	OK	6,44
	29/08/2022	26	OK	OK	OK	OK	OK	6,44
	05/09/2022	27	OK	OK	OK	OK	OK	6,45
	12/09/2022	28	OK	OK	OK	OK	OK	6,45
	19/09/2022	29	OK	OK	OK	OK	OK	6,45
	26/09/2022	30	OK	OK	OK	OK	OK	6,46
	03/10/2022	31	OK	OK	OK	OK	OK	6,46
	10/10/2022	32	OK	OK	OK	OK	OK	6,47
	17/10/2022	33	OK	OK	OK	OK	OK	6,47
	24/10/2022	34	OK	OK	OK	OK	OK	6,48
	31/10/2022	35	OK	OK	OK	OK	OK	6,50
	07/11/2022	36	OK	OK	OK	OK	OK	6,50
Variation from initial value %								1,6
Conclusion								Pass

- : Not tested

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Customer	**MOBILEFRESH AG**
Product	**MEDI CLEAN**
Conditions	**DARK/WINDOW**
Lab ID	**22 26 00027**
Manufacture batch	**V1.0**
Manufacture date	**N/A**
Stability Start date	**28/02/2022**

START DATE	WEEKS	DARK				WINDOW			
		APPEARANCE	ODOR	COLOR	TEXTURE	APPEARANCE	ODOR	COLOR	TEXTURE
7/2/2022	0	OK	OK	OK	OK	OK	OK	OK	OK
14/2/2022	1	OK	OK	OK	OK	OK	OK	OK	OK
21/2/2022	2	OK	OK	OK	OK	OK	OK	OK	OK
28/2/2022	3	OK	OK	OK	OK	OK	OK	OK	OK
7/3/2022	4	OK	OK	OK	OK	OK	OK	OK	OK
14/3/2022	5	OK	OK	OK	OK	OK	OK	OK	OK
21/3/2022	6	OK	OK	OK	OK	OK	OK	OK	OK
28/3/2022	7	OK	OK	OK	OK	OK	OK	OK	OK
4/4/2022	8	OK	OK	OK	OK	OK	OK	OK	OK
11/4/2022	9	OK	OK	OK	OK	OK	OK	OK	OK
18/4/2022	10	OK	OK	OK	OK	OK	OK	OK	OK
25/4/2022	11	OK	OK	OK	OK	OK	OK	OK	OK
2/5/2022	12	OK	OK	OK	OK	OK	OK	OK	OK
30/05/2022	13	OK	OK	OK	OK	OK	OK	OK	OK
06/06/2022	14	OK	OK	OK	OK	OK	OK	OK	OK
13/06/2022	15	OK	OK	OK	OK	OK	OK	OK	OK
20/06/2022	16	OK	OK	OK	OK	OK	OK	OK	OK
27/06/2022	17	OK	OK	OK	OK	OK	OK	OK	OK
04/07/2022	18	OK	OK	OK	OK	OK	OK	OK	OK
11/07/2022	19	OK	OK	OK	OK	OK	OK	OK	OK
18/07/2022	20	OK	OK	OK	OK	OK	OK	OK	OK
25/07/2022	21	OK	OK	OK	OK	OK	OK	OK	OK
01/08/2022	22	OK	OK	OK	OK	OK	OK	OK	OK
8/08/2022	23	OK	OK	OK	OK	OK	OK	OK	OK

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15/08/2022	24	OK	OK	OK	OK	OK	OK	OK	OK
22/08/2022	25	OK	OK	OK	OK	OK	OK	OK	OK
29/08/2022	26	OK	OK	OK	OK	OK	OK	OK	OK
05/09/2022	27	OK	OK	OK	OK	OK	OK	OK	OK
12/09/2022	28	OK	OK	OK	OK	OK	OK	OK	OK
19/09/2022	29	OK	OK	OK	OK	OK	OK	OK	OK
26/09/2022	30	OK	OK	OK	OK	OK	OK	OK	OK
03/10/2022	31	OK	OK	OK	OK	OK	OK	OK	OK
10/10/2022	32	OK	OK	OK	OK	OK	OK	OK	OK
17/10/2022	33	OK	OK	OK	OK	OK	OK	OK	OK
24/10/2022	34	OK	OK	OK	OK	OK	OK	OK	OK
31/10/2022	35	OK	OK	OK	OK	OK	OK	OK	OK
07/11/2022	36	OK	OK	OK	OK	OK	OK	OK	OK

- : Not tested

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Customer	**MOBILEFRESH AG**
Product	**MEDI CLEAN**
Conditions	**-20°C/8h to +25°C/16h**
Lab ID	**22 26 00027**
Manufacture batch	**V1.0**
Manufacture date	**N/A**
Stability Start date	**28/02/2022**

START DATE	CYCLES	TIME	APPEARANCE	ODOR	COLOR
28/02/2022	END RT	09:00	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK
01/03/2022	END RT	09:00	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK
02/03/2022	END RT	09:00	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK
03/03/2022	END RT	09:00	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK
04/03/2022	END RT	09:00	OK	OK	OK
	END FREEZING	16:00	OK	OK	OK

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CONCLUSION

The following aspects of the product were evaluated within the frame of this study:

- ✓ Organoleptic: appearance, color, odor and texture
- ✓ Physical-chemical: pH, assay of preservatives
- ✓ Compatibility between product and container

At the end of the stability study the product was tested for phthalates with the below results:

Benzyl Butyl Phthalate <1 mg/kg

Di-n-Butyl Phthalate <1 mg/kg

Diethylhexyl Phthalate <1 mg/kg

Di (2-methoxyethyl) Phthalate <1 mg/kg

Di-n-Pentyl Phthalate <1 mg/kg

Diisobutyl Phthalate <1 mg/kg

The findings presented in the current study confirm that the product "**MEDI CLEAN**" presented satisfactory sensorial, physical and chemical characteristics, for a period of 9 months under accelerated storage conditions. Additionally, the product presented acceptable compatibility with its final container.

The product was tested in real time for 9 months (real use of the product was stimulated). Additionally, the product was tested under accelerated conditions for 9 months. At each testing interval a new package was used and then discarded. In theory, a temperature increase of 10 degrees doubles the rate of a reaction.

Taking into consideration the above stability study, a shelf life of 36 months can be attributed to the product.

Study Manager: Panagiota Tsafara
Printed name: Panagiotis Nikolakis BSc.
Date: 14/12/2022

Results refer to the sample as received and analyzed on the period specified.

The test report shall not be reproduced except in full, without written approval of the laboratory.

The laboratory book which contains all the information (raw data and results) regarding the study and the study reports are kept in the laboratory archives during 2

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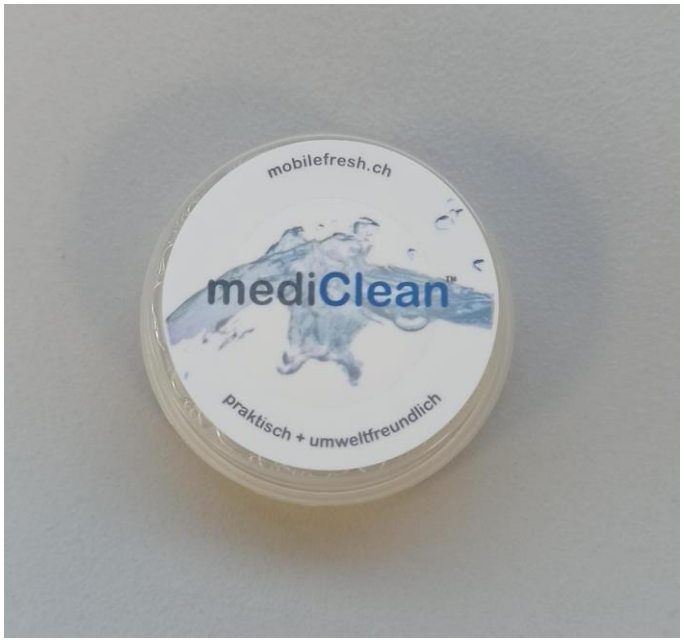
PHOTOS



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TEST REPORT
22 24 00409

PATCH TEST REPORT

MEDI CLEAN

MOBILEFRESH AG

MARCH 2022

Quality Assurance & Control Systems Ltd.,1 Antigonis St., 144 51, Athens, Greece
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48 HOURS PATCH TEST
SKIN TOLERANCE ASSESSMENT
STUDY REPORT

CERTIFICATE ID	: 2022-2106 / 22 24 00409
DISTRIBUTOR	: N/A
PRODUCT MANUFACTURED BY	: MOBILE FRESH AG
RECEIPT DATE	: 21/2/2022
STUDY PERIOD	: 2/3/2022 - 8/3/2022
LAB ID	: 22 24 00409
PRODUCT NAME	: MEDI CLEAN
BRAND	: N/A
PRODUCT TYPE	: RINSED, CLEANSER
LOT	: V01.22
STUDY SPONSOR	: MOBILEFRESH AG
METHOD	: 48 Hours occlusive patch tests

ASSESSMENT OF SKIN TOLERANCE OF A COSMETIC PRODUCT AFTER A SINGLE APPLICATION DURING 48 HOURS OCCLUSIVE PATCH ON 20 VOLUNTEERS

TABLE OF CONTENTS

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REGULATORY, CONFIDENTIALITY AND ARCHIVING

Regulatory

The study has been conducted by suitably trained, qualified and experienced personnel in accordance with the Declaration of Helsinki (1964) and subsequent revisions (World Medical Association, 1989, Council for International Organizations of Medical Sciences and the World Health Organization, 1993) and taking into consideration the requirements of Directives 2001/20/EC and 2005/28/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use and the COLIP A Guidelines edited on 1997 for the "Product T est Guidelines for the Assessment of Human Skin Compatibility".

Precautions have been taken to avoid the possibility that participants in the study might experience undesirable effects.

Ethical requirements which have been taken into consideration in the planning of the study include:

i) participants are informed volunteers selected after application of inclusion/non inclusion criteria

ii) participants are aware of the purpose and nature of the study and of any foreseeable risks involved in participation in the study and have given written informed consent before the study starts;

iii) a safety evaluation /INCI review has been conducted on the product tested, before the study starts.

iv) the test procedures conforms to national regulations.

v) all reasonable care has been taken to avoid causing excessive skin reactions or other adverse health effects in the participants during the study;

vi) safety procedures are in place in the event of any unexpected/adverse reactions, including appropriate medical cover;

vii) volunteers are rewarded for their time, inconvenience, etc., but the reward is not so great that it would persuade them to participate.

Confidentiality

Requirements of Law 2472/1997 on the Protection of Individuals with regard to the Processing of Personal Data and of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and amendments are taken into consideration. Processing of volunteers' personal data is carried out by doctors or other persons rendering medical services, provided that the Controller is bound by medical confidentiality or other obligation of professional secrecy, provided for in Law or code of practice, and data are neither transferred nor disclosed to third parties. Processing is carried out within the laboratory premises and relates to personal data of the volunteers, provided that the latter have given their consent and that such data are neither transferred nor disclosed to third parties. The anonymity of the volunteers is respected, no personal records have been kept apart from the ones required from National and European Laws. Each volunteer can be identified by the Investigator, the doctors and all the persons in charge of the study, thanks to his personal volunteer's code.

Archiving

The laboratory book which contains all the information (raw data and results) regarding the study and the study reports are kept in the laboratory archives for 2 years.

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STUDY SUMMARY / ABSTRACT

ASSESSMENT OF SKIN TOLERANCE OF A COSMETIC PRODUCT AFTER A SINGLE APPLICATION DURING 48 HOURS OCCLUSIVE PATCH ON 20 VOLUNTEERS

CERTIFICATE ID	: 2022-2106 / 22 24 00409
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LAB ID	: 22 24 00409
PRODUCT NAME	: MEDI CLEAN
BRAND	: N/A
PRODUCT TYPE	: RINSED, CLEANSER
LOT	: V01.22
STUDY SPONSOR	: MOBILEFRESH AG
TEST METHOD	: Single application - 48 Hours occlusive patch tests
TIME(S) OF ASSESSMENT	: 1 hour after patch removal, then after 24 & 48 hours (72 hours)
PANEL	: 20 healthy adult volunteers
APPLICATION AREA	: On the back
QUANTITY OF PRODUCT	: 0.02 ml
METHODOLOGY	: Patch test is the assessment of skin tolerance of a cosmetic product and involves a single application during 48 hour occlusive patch test. Negative controls are used to facilitate evaluation. Treatment sites are assessed before the first application of the test material (baseline), after treatment at 30 minutes, upon patch removal and at 24 and 48 hours after patch removal. The patch is applied on the skin for 48 hours. Skin reactions are scored throughout the test by the same experienced assessor, a dermatologist, who made the baseline assessment and under the same lighting source, following a pre-defined scoring scale. The quantification of the skin irritation is given through a numeric scale (erythema, oedema, dryness/desquamation, vesicles). The average irritant score of the product tested is calculated from the average of the reactions obtained for each volunteer, allowing to rank the product from "non irritant to very irritant".
RESULT	: The average irritant score of the product is 0.00.
CONCLUSION	: According to the experimental conditions of the study, the test product, can be considered as **Non irritant** regarding Its primary skin tolerance.

The samples will be stored by the laboratory for 2 months from the end test date.
The study report and raw data will be stored by the laboratory for 2 years.

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TYPE AND OBJECTIVE OF THE STUDY

Skin compatibility is defined as the absence of skin irritation under normal conditions of use and reasonably foreseeable misuse, taking into account objective reactions as well as subjective responses such as stinging, burning or itching.
Skin irritation is defined as non -immunological local skin inflammation.

This test involves single application, 48 hour occlusive patch test.
Small quantity (0.02mL) of the finished product is applied in an occlusive patch. The patch is then applied on adult volunteers, directly on the skin of their back, for 48 hours.
After the patch is removed, the dermatologist performs a clinical evaluation based on a pre -determined scale.
The objective of the test is to determine whether or not the product is likely to induce skin irritation under normal conditions of use and reasonably foreseeable misuse conditions.

PANEL STUDIED, INCLUSION / NON INCLUSION CRITERIA.

Number of volunteers
A number of 20 volunteers has been recruited to satisfy the objectives of the test.

Panel characteristics
Volunteers are selected on the basis of inclusion and non -inclusion criteria. The volunteers satisfy all the inclusion criteria and are not in conflict with any of the non -inclusion criteria, had a medical examination (health certificate) and a dermatological examination. The volunteers are clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They give their written informed consent before participation in the study.

Inclusion criteria

- ✓ Informed volunteers who agree to follow the conditions specified
- ✓ where appropriate of relevant age : 18 -70 years old
- ✓ where appropriate of relevant gender : female and/or male
- ✓ where appropriate of relevant origin and health
- ✓ free from any dermatological problems on the area studied
- ✓ meet the specific study criteria on skin type
- ✓ able to understand the Greek langu age and the study requirements

Non inclusion criteria

- ✓ volunteers who do not meet the inclusion criteria
- ✓ pregnancy or nursing condition
- ✓ irritated skin on test site(s)
- ✓ blemishes, marks (e.g. tattoos, scars, sunburn) on the test site(s)
- ✓ medication which may affect skin response and/or past medical history
- ✓ presenting skin pathology which may interfere with the aim(s) of the study
- ✓ presenting contact allergy to one of the ingredients of the tested product
- ✓ participation in another simultaneous study
- ✓ participation in a previous study without an appropriate rest period between studies
- ✓ minors or majors protected by the law and people admitted in a sanitary or social institution for other purpose than research
- ✓ persons deprived of liberty by legal or administrative decision, patients in emergency situation
- ✓ volunteers who refused to give their informed consent.

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Study constraints

During the study, the volunteers are asked:

- ✓ Not to put any product or water on the patches area.
- ✓ Not to expose themselves to UV.
- ✓ To avoid all intense sportive activities that could remove the patch.
- ✓ Not to take aspirin, anti-histaminics, corticoids, anti-inflammatories and any other treatment decreasing or avoiding inflammations or allergies or interfering with the skin metabolism.

Volunteers withdrawals

Participants will be eliminated for the following reasons:

- ✓ they do not follow the conditions of the Study Information Sheet;
- ✓ they suffer any illness or accident or develop any condition during the study which could affect the outcome of the study;
- ✓ they no longer wish to participate in the study.

TEST MATERIAL

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LAB ID	: 22 24 00409
PRODUCT NAME	: MEDI CLEAN
BRAND	: N/A
PRODUCT TYPE	: RINSED, CLEANSER
LOT	: V01.22
STUDY SPONSOR	: MOBILEFRESH AG
STORAGE CONDITIONS	: Away from heat and light

A sample of the tested product is kept at the QACS laboratories for 2 months after the end of the study. After this date and unless contrary requirement from the study sponsor, the product will be destroyed.

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Equipment

The equipment used for the occlusive patch is composed of a small plastic cavity of 0.64 cm^2 with a filter tissue at the bottom which is made to receive the product to test. All this is fixed to a hypoallergenic non woven adhesive tape.

Dose level

The amount of test material applied to each patch is sufficient to fill the chamber and saturate the pad without overflowing from it when applied to the skin.

Test material application

The area on which the patch is applied is previously cleaned up with demineralised water and dried with cellulose cotton wool tissue.

The patches are put on the back of the volunteer.

The products are tested pure or diluted depending on their type and their use.

- ✓ Leave on products are tested pure.
- ✓ Rinse-off products are tested diluted at 5%.
- ✓ Detergents are tested diluted at 10%.
- ✓ Hydrophilic products are diluted in demineralised water
- ✓ Lipophilic products are diluted in mineral oil.
- ✓ Powders are put pure in the patch small cavity and then moistened sufficiently with a drop of mineral oil in order to ensure good contact with the skin and avoid the product dispersion while applying the patch.

Negative controls

Whilst this activity is always be on a case -by-case basis and will depend on the nature and type of study, the most common approach is to compare the results obtained for the test materials with those of suitable negative controls, or with similar materials.

A "negative" control is a patch without any product, applied in the same conditions as the product to be tested:

- ✓ if the product is tested pure: empty patch.
- ✓ if the product is tested diluted: patch with 0.02ml of the solvent used (demineralised water or mineral oil).

Visual assessment

Treatment sites are assessed before the first application of test material (baseline) and 30 minutes after patch application and 1, 24 and 48 hours after removal of the patches (the patches are left on the skin for 48 hours). Negative controls are used to facilitate evaluation.

Skin reactions are scored throughout the test by the same experienced assessor who made the baseline assessment and under the same lighting source, following a pre -defined scoring scale.

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EXAMPLE OF SCORING SCALE

ERYTHEMA

0 = no evidence of erythema

0.5 = minimal or doubtful erythema

1 = slight redness, spotty and diffuse

2 = moderate, uniform redness

3 = strong uniform redness

4 = fiery redness

DRYNESS (SCALING)

0 = no evidence of scaling

0.5 = dry without scaling; appears smooth and taut

1 = fine/mild scaling

2 = moderate scaling

3 = severe scaling with large flakes

OEDEMA

- = absence of oedema

+ = presence of oedema

EXAMPLE OF SCORING SCALE

The results obtained are compared to those obtained on the control zone. The Average Irritation Index (or Primary Skin Irritation) is calculated as the average of readings obtained on the volunteers population.

$$\frac{\left[\sum(\text{marks T48})_{\text{vol 1 to vol n}}\right] / \text{number of readings}}{\text{Number of volunteers}}$$

Classification of the irritant potential

Average irritation index	Classification
0 - 0.08	Non irritant
0.08 - 0.16	Very slightly irritant
0.16 - 0.56	Slightly irritant
0.56 - 1	Moderately irritant
1 - 1.16	Irritant
> 1.16	Very irritant

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RESULTS

Panel description

This study includes 20 healthy adult volunteers whom characteristics are described below.

Volunteers characteristics

VOL ID	VOLUNTEER CODE	SEX	AGE	CHARACTERISTICS	Events occured during the study
1	1287	F	31	Sensitive skin	
2	1932	M	26	Sensitive skin	
3	2157	F	58	Sensitive skin	
4	2222	F	30	Sensitive skin	
5	2290	F	63	Sensitive skin	
6	2477	M	48	Sensitive skin	
7	2486	F	55	Sensitive skin	
8	2489	F	20	Sensitive skin	
9	2561	F	18	Sensitive skin	
10	2585	M	30	Sensitive skin	
11	2609	F	26	Sensitive skin	
12	2622	F	29	Sensitive skin	
13	2641	F	52	Sensitive skin	
14	2653	F	19	Sensitive skin	
15	2663	F	21	Sensitive skin	
16	2675	F	20	Sensitive skin	
17	2678	F	63	Sensitive skin	
18	2679	F	30	Sensitive skin	
19	2692	F	58	Sensitive skin	
20	2693	F	55	Sensitive skin	

Study withdrawals

None.

Skin reactions on the reference area

No skin reaction was noticed by the dermatologist on the reference area for all the volunteers.

Results analysis

Results obtained for each volunteer as well as the corresponding irritation index.

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STUDY SPONSOR	: MOBILEFRESH AG
STORAGE CONDITIONS	: Away from heat and light

VOL ID	VOLUNTEER CODE	SEX	AGE	**ERYTHEMA**	**DRYNESS**	**OEDEMA**	Total readings 48hrs
1	1287	F	31	0	0	0	0
2	1932	M	26	0	0	0	0
3	2157	F	58	0	0	0	0
4	2222	F	30	0	0	0	0
5	2290	F	63	0	0	0	0
6	2477	M	48	0	0	0	0
7	2486	F	55	0	0	0	0
8	2489	F	20	0	0	0	0
9	2561	F	18	0	0	0	0
10	2585	M	30	0	0	0	0
11	2609	F	26	0	0	0	0
12	2622	F	29	0	0	0	0
13	2641	F	52	0	0	0	0
14	2653	F	19	0	0	0	0
15	2663	F	21	0	0	0	0
16	2675	F	20	0	0	0	0
17	2678	F	63	0	0	0	0
18	2679	F	30	0	0	0	0
19	2692	F	58	0	0	0	0
20	2693	F	55	0	0	0	0

Total reactions 48hrs. all volunteers	**0**
Number of readings	**1**
Total irritation / number of readings	**0**
Irritation index	**0.00**
Result	**Non irritant**

After 48 hours of application, no skin reaction was observed, by the dermatologist on the test area.
The average irritation index obtained is equal to 0.00.
Readings are performed at 1, 24 and 48 hours after removal of the patches.

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RESULTS (continued)

DISCUSSION AND CONCLUSION

In the experimental conditions, after a single application of 0.02 ml of the product under occlusive patch and during 48 hours, on 20 healthy adult volunteers and according to the scale used for the interpretation of the results, the MEDI CLEAN can be considered as Non irritant regarding its primary skin tolerance.

The above study was conducted on volunteers with sensitive skin.

Michail Tsanakas
Dermatologist - Venereologist

Michail Tsanakas
Date : 8/3/2022

RESULTS AUTHENTICITY

The study concerned by this report was carried out under my responsibility, according to the experimental protocol and the quality plan of the QACS Ltd laboratory, and follows the good clinical practices.
All the observations and data recorded during this trial are reported in this study report.

I certify the rereading of this report and do agree with its content

anager :

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Georgia Stamatopoulou
Date : 8/3/2022

This document has been electronically signed by those names that appear on this report and are the authorized signatories.

The samples will be stored by the laboratory during 1 month from the end test date.
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CERTIFICATE No : **2025-9696 / 25 03 11917**

CERTIFICATE OF ANALYSIS

CUSTOMER NAME : MOBILEFRESH AG

		Sampled by	: CLIENT
Sampling Date	: 17/06/2025	Start of Analysis	: 20/06/2025
Receipt Date	: 17/06/2025	End of Analysis	: 25/06/2025
		Sampling Location	: SWITZERLAND

Sample Code : 25 03 11917

SAMPLE DESCRIPTION : MEDICLEAN LOT: NOT LISTED

Sample condition on receipt: Normal, as specified on internal procedure GP508
Packaging type: Intermediate Bulk Container

PARAMETERS	METHOD	RESULT	UNITS	LIMITS
Total Aerobic Microbial Count	Eur Pharm 2.6.12	<10	cfu/g	<2.0E+02
Molds & Yeasts	Eur Pharm 2.6.12	<10	cfu/g	<2.0E+01
* Total coliforms	In house	Absence	-	Absence/1g
Staphylococcus aureus	Eur Pharm 2.6.13	Absence	-	Absence/1g
Pseudomonas aeruginosa	Eur Pharm 2.6.13	Absence	-	Absence/1g
* Hemolytic streptococcus	In house	Absence	-	Απουσία/1g

Microbiological limits according to European Pharmacopoeia 5.1.4 "Acceptance criteria for microbiological quality of non-sterile dosage forms for cutaneous use (Table 5.1.4-1)".

CONCLUSION: Within limits for the parameters tested.

When a test report includes a statement of conformity with a specific specification or standard, the applicable decision rule is applied. For further details, please refer to the relevant QACS document titled "Decision Rule", available on the official company website.

(*) Tests not in the current scope of accreditation under the terms of EN ISO/IEC 17025:2017.

For the laboratory

QACS Laboratories
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Lagiopoulos Giorgos

Head of Microbiology Department
Pharmaceutical Microbiologist MSc
Agronomist – Food Scientist MSc

Testing
No of Certificate 195

Signature Date: 27/06/2025
Signature Reason: Verification of Analysis Results
Edition Date: 27/06/2025

End of test certificate.

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CERTIFICATE No : **2025-9698 / 25 10 02947**

CERTIFICATE OF ANALYSIS

CUSTOMER NAME : MOBILEFRESH AG

		Sampled by	: CLIENT
Sampling Date	: 17/06/2025	Start of Analysis	: 26/06/2025
Receipt Date	: 17/06/2025	End of Analysis	: 26/06/2025
		Sampling Location	: SWITZERLAND

Sample Code : 25 10 02947

SAMPLE DESCRIPTION : MEDICLEAN LOT: NOT LISTED

Sample condition on receipt: Normal, as specified on internal procedure GP508
Packaging type: Intermediate Bulk Container

PARAMETERS	METHOD	RESULT	UNITS
# Chromium (Cr) VI	ICP-MS, Internal method XM113	<Reporting Limit (0.1)	mg/kg
Cadmium (Cd)	ICP-MS, Internal method XM113	<Reporting Limit (0.002)	mg/kg
Mercury (Hg)	ICP-MS, Internal method XM113	<Reporting Limit (0.02)	mg/kg
Lead (Pb)	ICP-MS, Internal method XM113	<Reporting Limit (0.02)	mg/kg

(#) Tests analyzed by a subcontractor.

For the laboratory

Panagiotis Nikolakis
Chemist BSc

QP
Signature Date: 26/06/2025

Signature Reason: Verification of Analysis Results
Edition Date: 26/06/2025

End of test certificate.