Cosming Lab
cosmetics analyses

48 HOURS CLOSE- 24 HOURS OPEN PATCH TEST

CLOOE FACE CLEANING FOAM

THRONES DANIŞMANLIK GIDA TEKSTİL VE DIŞ TİCARET LİMİTED ŞİRKETİ

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Sample storage period is only 1 week.
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Analysis carried out on samples of the procedure up to the delivery to our laboratory that received the specimen and maintaining the desired group and parameters to determine technical and legal responsibility belongs to the area of the sample.
Unsigned and unsealed analysis report is invalid.

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Customer Name	**: THRONES DANIŞMANLIK GIDA TEKSTİL VE DIŞ TİCARET LİMİTED ŞİRKETİ**
Address	: Fatih Sultan Mehmet Mah. Poligon Cad. No:8C İç Kapı No:1 Ümraniye/İSTANBUL
Kind of Sample	: Skin Cleansing Product
Brand of Sample	: CLOOE FACE CLEANING FOAM
Lot/ Series Number of Sample	: -
Production and Expiration Date of Sample	: - / -
Sample acceptance date	: 01.09.2021
Sample Storage Conditions	: Room Conditions- Away From Heat And Light
Study Sponsor	: Cosming Laboratuvar
Method	: 48 Hours Close- 24 Hours Open Patch Test
Volunteers	: 12
Analysis Start - Final Date	: 18-21.10.2021
Reporting date	**: 22.10.2021**

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Regulatory:

The study has been conducted by suitably trained, qualified and experienced personnel in accordance with the Declaration of Helsinki (1964) 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 COLIPA Guidelines edited on 1997 for the "Product Test 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.

1- Participants are informed volunteers selected after application of inclusion/non inclusion criteria, 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

2- Before starting study, the company which request this test, has been signed a declaration which is about their products safety.

3- The test procedures conforms to national regulations and "Turkish Medicines And Medical Devices Agency (TMMDA)'s The Guide of Human Skin Compatibility With Cosmetic Products Or Raw Materials Assessment " and "The Guide Of The Efficacy And Safety Studies Of Cosmetics And Raw Materials Which Tested On Volunteers" .

4- All reasonable care has been taken to avoid causing excessive skin reactions or other adverse health effects in the participants during the study.

Confidentiality Declaration:

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 data are neither transferred nor disclosed to third parties. The anonymity of the volunteers is respected within all studies carried out in our laboratories. 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 during 2 years.

Study Purpose, Procedure Summary:

Skin Irritation Tests: It is the test of cosmetic products or raw materials are caused skin irritation or not.

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 nonimmunological local skin inflammation.

A sample of 0,02 ml of cosmetic product applied to the back area of the volunteers is removed after 48 hours on the back, the first evaluation is made after half an hour, at the end of 72 hours under the same conditions 2. Evaluation is carried out and the results are graded by the dermatologist and responsible researchers. After the results are calculated according to the results, the result is interpreted not as irritant, but as a cause of irritation and very irritant, cause of high irritation. After the calculations are made according to the results, the result is interpreted between the non-irritant and very irritant.

Sterile patchs are used for this test. Before apply patchts, back area cleaned using deionized water and dried with cotton.

Mostly, the products are tested pure. Leave-in products are to be applied directly 0.02 ml or g. Powders are put pure in the patch small cavity and then moistened sufficiently with a drop of mineral oil in order to to ensure good contact with the skin and avoid the product dispersion while applying the patch. Detergents are tested diluted at 10%. Rinseoff products are tested diluted at 5%. Hydrophilic products are diluted in demineralised water, Lipophilic products are diluted in mineral oil.

Volunteer Consent:

Participants are informed volunteers selected after application of inclusion/non inclusion criteria, 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

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, free from presenting contact allergy to one of the ingredients of the tested product)
- Free from any dermatological problems on the area studied able to understand the Turkish language and the study requirements

Non inclusion criteria

- Volunteers who does 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(7 days) between studies
- Persons deprived of liberty by legal or administrative decision, patients in emergency situation
- Volunteers who refused to give their free and informed consent.

The Benefits And Challenges Of The Study

Benefits expected from the study; monitoring of cosmetic products, which will be released or which had, are caused skin irritation or not, and based on the analysis results,ensuring consumer safety.

Challenges Of The Study; the average irritant score of the product to be tested is calculated from the average of the quotations obtained for each volunteer, allowing to rank the product from "non irritant to very irritant". So, It can caused erythema, oedema, dryness/desquamation, vesicles.

- When volunteers feel, excessive burning, itching and discomfort,they can remove the plaster,but they have to note that removing date-time, and notify stuations and date-time information to the principal investigator.
- Not to put any product, also water on the patches area.
- Not to have a bath, neither to expose themselves to UV.
- To avoid all intense sportive activities that could remove the patch.
- Not to take aspirin, antihistaminics, corticoids, antiinflammatories and any other treatment decreasing or avoiding inflammations or allergies or interfering with the skin metabolism.

Volunteers withdrawals:

- 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.

Assessment:

The evaluation is done visually by the investigator and the dermatologist who is an expert in the field. Evaluations are based on the observation and comparison of 3 conditions before and after the application (at 0 hours), at the end of 48 hours and at the end of 72 hours. Negative controls aim to facilitate comparisons. The results are made according to the predetermined scores and the results are calculated by taking the average of the results.

Skoring:

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

+	: Presence of oedema
-	: Absence of oedema

$$\frac{\sum \text{volunteer's data / Number of readings}}{\text{Number of volunteers}}$$

Classification Criteria:

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
1-1.6	Irritant
>1.6	Very irritant

Volunteers characteristics:

NU	VOLUNTEERS ID	SEXUALITY	AGE	SKIN TYPE	EVENTS OCCURED DURING THE STUDY
1	CL420	F	23	Normal Skin	NA
2	CL422	F	36	Normal Skin	NA
3	CL424	M	25	Normal Skin	NA
4	CL430	F	20	Normal Skin	NA
5	CL440	F	39	Normal Skin	NA
6	CL446	F	20	Normal Skin	NA
7	CL448	F	49	Normal Skin	NA
8	CL458	F	25	Normal Skin	NA
9	CL461	F	41	Normal Skin	NA
10	CL462	M	24	Normal Skin	NA
11	CL464	F	35	Normal Skin	NA
12	CL468	M	38	Normal Skin	NA

The Study Incidents

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

No withdrawal of the study happened.

Results Table:

NU	VOLUNTEERS ID	SEXUALITY	AGE	NEGATIVE CONTROL	48. HOURS RESULTS			72. HOURS RESULTS		
					ERYTHEMA	DRYNESS	OEDEMA	ERYTHEMA	DRYNESS	OEDEMA
1	CL420	F	23	-	0	0	-	0	0	-
2	CL422	F	36	-	0	0	-	0	0	-
3	CL424	M	25	-	0	0	-	0	0	-
4	CL430	F	20	-	0	0	-	0	0	-
5	CL440	F	39	-	0	0	-	0	0	-
6	CL446	F	20	-	0	0	-	0	0	-
7	CL448	F	49	-	0	0	-	0	0	-
8	CL458	F	25	-	0	0	-	0	0	-
9	CL461	F	41	-	0	0	-	0	0	-
10	CL462	M	24	-	0	0	-	0	0	-
11	CL464	F	35	-	0	0	-	0	0	-
12	CL468	M	38	-	0	0	-	0	0	-

Calculation:

	48. Hours	72. Hours
Total Volunteers Data	0	0
Number of Readings	2	2
Total Volunteers Data / Number of Readings	0	0
Irritation index	0	0
Result	**Non irritant**	**Non irritant**

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CLOOE FACE CLEANING FOAM

"DERMATOLOGICALLY TESTED"

Discussion And Conclusion:

CLOOE FACE CLEANING FOAM was a rinse off product. Because of it, when it tested on volunteers, it diluted 5% with deionised water. The patches remained in the back area of the volunteers for 48 hours, the first measurements were made in half an hour after the patches were removed and the area left open 24 hours was re-evaluated in 72 hours. At the end of the 48th hour as a result of the evaluations and calculations the product is considered not irritant, At the end of the 72th hour as a result of the evaluations and calculations the product is considered not irritant.

Results Authenticity:

The study according to the experimental protocol and the quality plan of the Cosming Laboratuvar Bilgi Yön. Eğit. Dan. Koz. San. Tic. Ltd. Şti., concerned by this report was carried out under responsibility of that investigators, which is signed that report.
All the observations and data recorded during this trial are reported in this study report.
We certify the rereading of this report and do agree with its content.

Principal Investigator:

Laboratory Manager
MSc Chem. Aylin KAHRIMAN

Principal Investigator:

Laboratory Specialist
Microbiologist Cansu AYDOĞAN

Dermatologist:

Dr. Abdullah ÖZTÜRK