

STUDY REGARDING EFFICACY OF A COSMETIC ANTI-WRINKLE EYE CONTOUR CREAM AND ITS SUBJECTIVE AND INSTRUMENTAL EVALUATION

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Aims

This study intended to check the skin and eye acceptability and to assess the cosmetic qualities and efficacy of the product **ANTI WRINKLE EYE CONTOUR CREAM**, after repeated applications on face, including eye contour, after application under normal conditions of use for 28 consecutive days, on a panel of 20 women.

This cream contains two active natural ingredients of plant origin obtained by cold pressing, namely: Argan oil fatty [Argania spinosa) and fatty oil from flaxseed [Linum usitatissimum.L].

Introduction

Body care products help the skin to regain properties after washing / etching using reconstruction protective film or is to help skin become firmer and tonic.

Eye contour cream is mostly emulsions with plenty of water and some grease substances which are designed to moisturize and nourish the skin.

As in most cosmetic products on the market can find a number of controversial ingredients such as preservatives critics unidentified perfumes, oils and waxes of questionable quality, and recommended numerous little texture such as PEG, we proposed the formulation, implementation and testing of eye contour cream that contains two active ingredients of plant origin obtained by cold pressing, namely: Argania spinosa [9] [10] [11] [12] oil fatty and fatty oil from flaxseed [Linum usitatissimum.L] [5] [6] [7] [8].

This study intended to check the skin and eye acceptability and to assess the cosmetic qualities and efficacy of the product **ANTI WRINKLE EYE CONTOUR CREAM**, after repeated applications on face, including eye contour, after application under normal conditions of use.

Materials and methods:

The acceptability was:

- checked every day, by the volunteers themselves at home,
- controlled after visual examination of the experimental area, by the dermatologist or the responsible technician, after examination of the eye mucous membrane and periorcular area by an ophthalmologist and after questioning of the volunteers. (Matthies, 1991; Strube et al, 1989)

The anti-wrinkle effect was assessed *objectively* after taking of replicas (Frosch et al, 1993) before and after 28 consecutive days of treatment and image analysis with computer (Visioline[®] VL 650 software from Courage Khazaka in coloboration with Monaderm).

The *subjective* cosmetic qualities and efficacy were assessed, at the end of the study, using a target questionnaire.

Subjects

- Number of subjects defined in the protocol: 20
- Number of subjects' whose data were exploitable: 20 (20 subjects were included in the study, no volunteer discontinued and no exclusion was decided by the investigator).

Specific inclusion criteria

- Age: 35 - 60 years,
- Sex: feminine,
- phototype (Fitzpatrick): II – IV,
- all type of skin on face,
- having wrinkles and little wrinkles on the crow's-feet areas, according to the following scale:
 0 – absence of wrinkles and/or little wrinkles
 1 – light wrinkle condition

- 2 – moderate wrinkle condition on at least one crow’s-foot area
- 3 – moderate wrinkle condition on both crow’s-foot areas - using regularly or occasionally face care products.

The experimental conditions were the following ones [1], Table no.1:

Table no.1. The experimental conditions of the test

Experimental area Applications at home	Product directions for use	Application at the Investigator center	Frequency/ duration
Face including peri-ocular area	Application of the product on face, by gentle digital massage, twice a day, in the morning and in the evening, on the clean face including the peri-ocular area	The first application on D1 by the subject himself under technician control after taking the replicas.	Second application on D1 in the evening from D2 till D28 twice a day in the morning and in the evening for 27 consecutive days+/- 2 days

The subjects were requested to note every day any reaction observed and any sensation of discomfort felt on the *individual observation sheet* that were given at the beginning of the study.

The skin examination of the experimental area was performed by the dermatologist or by the principal technician (Frosch et al, 1993, Pacsher, 1982)

This examination was performed visually under standard daylight source, at the beginning of the study and after 28 consecutive days of use.

The examination of peri-ocular area and of the eye mucous membrane was performed by an Ophthalmologist (Frosch et al, 1993, Pascher, 1982).

Concurrently with the clinical examination(s) performed after use of the product, each subject was questioned about the possible sensations of discomfort they felt.

Instrumental assessment of the anti-wrinkle effect

The skin relief was appreciated quantitatively, after taking of replicas and image analysis with computer, before and after treatment.

The anti-wrinkle effect of the test products was evaluated by comparison of the results obtained before and after 28 consecutive days of use.

Results

Table no.2. Checking the skin acceptability

Types of skin reactions ascribable to the test product	% of volunteers exhibiting clinical signs ascribable to the test product	Types of sensations of discomfort ascribable to the test product	% of volunteers exhibiting sensations of discomfort ascribable to the test product
None	0%	None	0%

Table no.3. Checking of eye compatibility

Types of eye reactions ascribable to the test product	% of volunteers exhibiting clinical signs ascribable to the test product	Types of sensations of discomfort ascribable to the test product	% of volunteers exhibiting sensations of discomfort ascribable to the test product
None	0%	None	0%

Instrumental assessment of the anti-wrinkle effect

The skin replicas analysis for the subjects’ ref. 12 and 18 were not exploitable because an experimental error occurred during the replica sampling.

The analysis was performed on a surface of 0.9659 cm².

Table no.4. Instrumental assessment of the anti-wrinkle effect

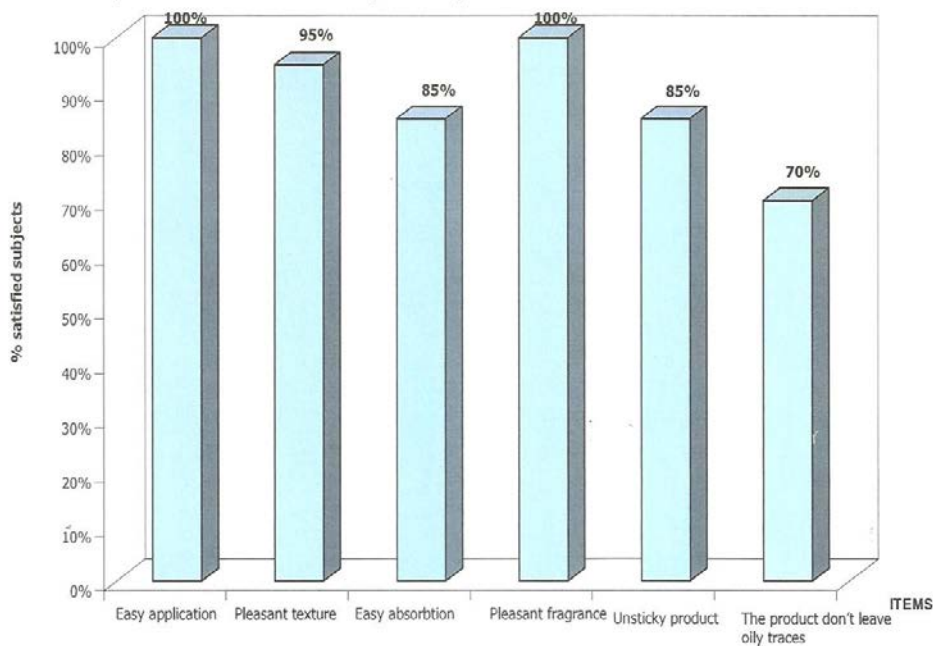
	Surface (ST) mm ²	WLength (LT) mm	Depth μm (PM)	Wrinkle (N)
D1				
N	18	18	18	18
Mean ± SD	34.52±23.26	1.40±0.31	164.54±33.10	59.67±26.05
D29				
N	18	18	18	18
Mean ± SD	22.31±16.82	1.36±0.32	162.15±34.07	49.94±26.75
D29-D1				
N	18	18	18	18
Mean ± SD	-12.21±22.19 -23.67%	-0.04±0.39 0.24%	-2.39±26.74 -0.52%	-9.72±23.79 -11.02%
test “t Student”				
p	0.016039	0.344159	0.354701	0.025054
Significance	S	NS	NS	S

S= significant (S for p<0.05 vs D1) NS= no significant

The product application during 28 consecutive days on a panel of 18 subjects contributed to the decrease of the wrinkles surface with a mean value of 12.21 mm² (23.67%) and to the decrease of the wrinkles number with a mean value of 9.72 (11.02%) and with a maximum of 48.

Cosmetic qualities: for each item, the number of satisfied subjects is reported below. In Graph no.1:

Graph no.1. Cosmetic qualities



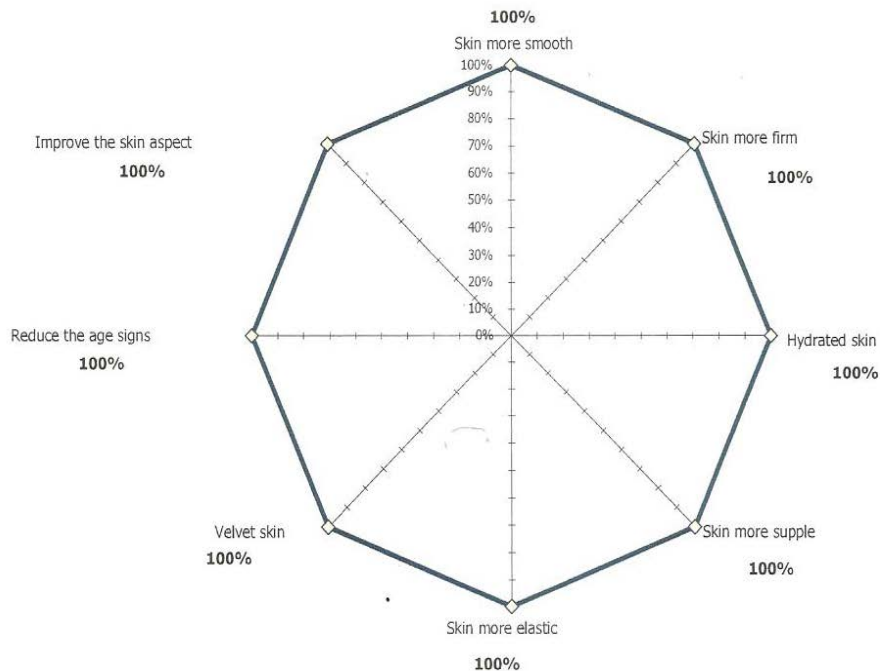
Regarding Cosmetics qualities, the test demonstrated the following aspects, as Table no.5:

Table no.5. Cosmetics qualities- % Satisfied subjects

Crt. No.	ITEM	% SATISFIED SUBJECTS

1.	Easy application, subjects' point de view	100%
2.	Pleasant texture, subjects' point de view	95%
3.	Easy absorption, subjects' point de view	85%
4.	Pleasant fragrance, subjects' point de view	100%
5.	Unstick product, subjects' point de view	85%
6.	The product doesn't leave oily traces, subjects' point de view -	70%

Cosmetic efficacy: for each item, the number of satisfied subjects is reported below, in Graph no.2. Cosmetic efficacy:
Graph no.2. Cosmetic efficacy



Regarding Cosmetics efficacy, the test demonstrated the following aspects as Table no.6:

Table no.6. Cosmetics efficacy - % Satisfied subjects

Crt. No.	ITEM	% SATISFIED SUBJECTS
1.	Skin more smooth, subjects' point de view	100%
2.	Skin more firm, subjects' point de view	100%
3.	Hydrated skin, subjects' point de view	100%
4.	Skin more supple, subjects' point de view	100%
5.	Skin more elastic, subjects' point de view	100%
6.	Velvet skin, subjects' point de view	100%
7.	Reduce the age signs, subjects' point de view	100%
8.	Improve the skin aspect, subjects' point de view	100%

CONCLUSIONS

According to the experimental conditions adopted and taking into the grading scales established by the investigator center the product **ANTI WRINKLE EYE CONTOUR CREAM** has a very good skin and eye acceptability.

It's very good skin and eye tolerance was thus confirmed.

The anti-wrinkle effect asses by image analysis with the Visioline[®] VL 650 software from Courage Khazaka in coloboration with Monaderm showed a significant effect in:

- (1) decrease of the wrinkles surface with a mean value of 12.21 mm² (23.67%);
- (2) decrease of the wrinkles number with a mean value of 9.72 (11.02%) and with a maximum of 48.

In other respects, the product was very well appreciated for the **cosmetic qualities** and more especially for easy application and pleasant fragrance.

After 28 days of use all the subjects appreciated the product efficacy for all the items.

Under the experimental conditions adopted the product can claim:

- “tested under dermatological and ophthalmological control”
- “safe for human health when applied under normal conditions of use”
- “very good skin and eye acceptability under normal conditions of use”
- “anti-wrinkle effect for light wrinkles” after 28 consecutive days of use.

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