Farcoderm
TESTED WELLNESS

In collaboration with:
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CLINICAL TEST AIMED AT EVALUATING THE TOLERABILITY AND SAFETY OF A COSMETIC PRODUCT USED IN THE PERIOCULAR AREA

BIOSELECT

BABY HAPPY HOUR
BABY'S SHAMPOO & SHOWER MILK

INDEX

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STUDY DESIGN

Title

Clinical test aimed at evaluating the tolerability and safety of a cosmetic product used in the periocular area.

Aim of the study

The test allows to assess whether the tested cosmetic product is tolerated and safe in the eye area. Product safety is tested through the analysis of side effects that may occur during the product use (lacrimation, redness, itching, burning).

Eye is a very delicate and vulnerable organ. Many anatomical elements naturally protect it: it is hollow in the eye socket, below frontal bones, and it has a great elasticity to lessen bumps and blunt traumas.
Eyelids represent a defence system too, because they protect the external eye area from foreign bodies and all irritating substances present in the environment. Furthermore, their continuous blinking allows to spread the fluids produced by lacrimal and conjunctival glands on the cornea, with lubricating, bactericidal and detergent functions able to maintain corneal transparency.
Conjunctiva is a mucous membrane covering the back surface of the eyelid and anterior portion of the eyeball: due to its lymphatic component, it is considered a lymph node covered by epithelium, able to react to different types of stimuli. Because of the extreme eye sensitivity to external elements and the stressful conditions which not infrequently is exposed (contact lenses, make-up, sun exposure, ...), it is important to pay close attention to this organ reactions, as they may be a symptom of serious damage.
During the study period, the experimenter asks the volunteers about the onset of symptoms such as lacrimation, burning, itching, redness, irritating sensations that occurred after product application. Any adverse reactions towards the product lead to treatment interruption and specific controls, aimed to verify that no eye damages occurred (keratitis, blepharitis, conjunctivitis, chemosis). Here below the main changes that may occur to the eye mucosa:

- **Blepharitis** is an eyelid margin inflammation characterized by redness, swelling, crusts, scales and ulcers. There are two types of blepharitis: ulcerative if it is caused by bacterial infection (stapphylococcum, almost always) and non-ulcerative (squamous or seborrheic) with unknown causes, usually associated to skin and scalp seborrhoea (dandruff) or of allergic nature. The first manifestation is foreign body sensation, together with lacrimation and light sensitivity. Moreover, it is associated to itching, redness and swelling of eyelid margins.
- **Conjunctivitis** is the most common form of ocular inflammation. The most frequent symptoms are redness, strong lacrimation, mucous or mucopurulent secretion, eyelid swelling, photosensitivity and foreign body sensation. Sometimes conjunctivitis is caused by allergy to substances such as pollen, dust, cosmetics, food, pets such as cat, etc. In addition to the common symptoms, allergic conjunctivitis can be recognized by strong itching and conjunctiva swelling (chemosis), which sometimes is so evident and strong to frighten the patient or his/her family especially due to its sudden onset.
- **Cheratitis** is a cornea inflammation, it causes a lesion of the superficial layer of the cornea with pain, lacrimation, photosensitivity and foreign body sensation.

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Tested Product

Information provided by the Customer

- Product name:

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- The tested cosmetic product complies with REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30th November 2009 on cosmetic products (recast) (Text with EEA relevance) and its annexes.

- Qualitative INCI formula:
  Filed

Evaluated parameters

- Product tolerability
- Mucosa and skin alterations

Ethical requirements

The study was carried out in compliance with the following ethical requirements:

- All subjects participating in the study are healthy volunteers at least 18 years old.
- All subjects participating in the study are selected under dermatologist's supervision, according to inclusion/non-inclusion criteria (see respective paragraph "Inclusion criteria" and "Non- inclusion Criteria").
- Volunteer participation in the study is totally free.
- All subjects participating in the study are informed of the aim and nature of the study.
- All subjects participating in the study are informed of the potential risks involved.
- All subjects participating in the study signed their informed consent form at the beginning of the study.
- Before volunteers were exposed to the product to be tested, all relevant safety information about the product itself and each ingredient were collected and evaluated.
- All the study procedures are carried out in accordance with the ethical principles for medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and successive amendments)
- All necessary precautions were taken in order to avoid any adverse skin reactions.
- If any unexpected/adverse skin reactions occur, the dermatologist evaluates the severity of the reaction (reporting it on the data collecting sheet) and, if necessary, proceeds with the appropriate therapy.

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Subject selection

Volunteers recruitment

20 volunteers with sensitive eyes were recruited in order to take part in the test, in accordance with the following inclusion and non-inclusion criteria:

Inclusion criteria

- ☑ Caucasian female subjects
- ☑ Age over 18 years
- ☑ Healthy subjects
- ☑ No eye problems (red eyes, lacrimation, foreign body sensation) that could affect ophthalmologist evaluation
- ☑ Commitment not to use other similar products during the study period
- ☑ Subjects informed about test purposes

Non-inclusion criteria

- ✘ Subjects who do not fit the inclusion criteria
- ✘ Pregnant or breastfeeding women
- ✘ Subjects with dermatological problems in the test area
- ✘ Subjects undergoing pharmacological treatment (both locally and systemically)
- ✘ Subjects with a past history of contact dermatitis
- ✘ Positive anamnesis for atopy

Withdrawal criteria

The volunteers are withdrawn from the study if

- ✘ They do not follow the conditions required on the Study Information Sheet they receive after recruitment
- ✘ They suffer any illness, accidents or develop any conditions during the study which could affect the outcome of the study
- ✘ They no longer wish to participate in the study.

Product application method

The product has been applied for a month, at least once a day. The product has been used as a rinse-off daily face cleaner.

Test execution

Subjects' suitability to participate in the study is evaluated during the first visit, when they receive the product in question to be used every day. Each enrolled subject is instructed to immediately stop the treatment if any unwanted side effects occur and to immediately inform (also by telephone) the specialist about any discomforts that may be attributed to the use of the product itself. Then, the volunteer comes back to our centre after 15 and 30 days of product use, and the specialist evaluates, with volunteer's collaboration, if the product is tolerated and safe for skin and eye mucosa.

Ophthalmologic study evaluations

During the study period, the following parameters are considered:

- Lacrimation
- Vasodilatation (redness, hyperaemia)
- Foreign body sensation
- Photophobia
- Itching and/or burning
- Periocular swelling

The occurrence of these disorders could mean that the product in question is cause of serious alterations of the ocular mucosa such as: conjunctivitis, keratitis, blepharitis, chemosis, oedema and redness on the external eye area. Product safety evaluations are summarized according to the clinical score shown in the table below.

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Eyelid skin alterations		Conjunctival mucosa alterations	
No alteration	0	No alteration	0
Slight alteration	-2	Slight alteration	-2
Evident alteration	-4	Evident alteration	-4

Monitored checks

Volunteers use the product to be tested for 30 days and the evaluations are performed by the experimenter during the first visit (T0) and after 15 (T15) and 30 (T30) days of treatment.

Panel description on eye sensitivity

Enrolled volunteers are selected according to their self-perception of sensitive eyes, followed by a discussion with the ophthalmologist in order to identify any possible causes.

One of the most common symptoms related to eye sensitivity is photophobia, that is excessive light sensitivity and the aversion to sunlight or well-lighted areas. This leads to an adverse reaction to light, followed by lacrimation, discomfort and/or pain. Volunteers with fair eyes and skin are often more sensitive to light.

The most common sensitivity causes include: the use of glasses or contact lenses, dry eye syndrome, allergies that can be seasonal (spring and autumn) or annual (dust, mould, etc...), or related to the presence of a particular type of allergen (eg. cat hair). Other common situations that can lead to eye hypersensitivity conditions are tiredness, computer eye strain, driving car for a long time or a combination of these factors.

Often volunteers having one or more of the above conditions hardly tolerate even make-up, skin care or cleansing cosmetic treatments, showing adverse reactions such as burning, redness, swelling and/or lacrimation during product use.

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RESULTS

TABLE 1

Volunteer n°	Lacrimation	Vasodilatation	Foreign body sensation	Photophobia	Itching	Stinging eyes	Periocular swelling
T0							
1 A1643V	NO	NO	NO	NO	NO	NO	NO
2 P0602L	NO	NO	NO	NO	NO	NO	NO
3 C0544S	NO	NO	NO	NO	NO	NO	NO
4 C2582E	NO	NO	NO	NO	NO	NO	NO
5 F1429M	NO	NO	NO	NO	NO	NO	NO
6 P1368A	NO	NO	NO	NO	NO	NO	NO
7 V2222D	NO	NO	NO	NO	NO	NO	NO
8 D2313T	NO	NO	NO	NO	NO	NO	NO
9 M1811M	NO	NO	NO	NO	NO	NO	NO
10 M0251V	NO	NO	NO	NO	NO	NO	NO
11 S1458A	NO	NO	NO	NO	NO	NO	NO
12 S2708F	NO	NO	NO	NO	NO	NO	NO
13 C1421F	NO	NO	NO	NO	NO	NO	NO
14 P0606M	NO	NO	NO	NO	NO	NO	NO
15 M1721L	NO	NO	NO	NO	NO	NO	NO
16 D0785A	NO	NO	NO	NO	NO	NO	NO
17 G1408M	NO	NO	NO	NO	NO	NO	NO
18 S2354S	NO	NO	NO	NO	NO	NO	NO
19 A2458S	NO	NO	NO	NO	NO	NO	NO
20 R0335H	NO	NO	NO	NO	NO	NO	NO

Table 1 summarizes the ophthalmological evaluation at T0 time

TABLE 2

Volunteer n°	Lacrimation	Vasodilatation	Foreign body sensation	Photophobia	Itching	Stinging eyes	Periocular swelling
T15							
1 A1643V	NO	NO	NO	NO	NO	NO	NO
2 P0602L	NO	NO	NO	NO	NO	NO	NO
3 C0544S	NO	NO	NO	NO	NO	NO	NO
4 C2582E	NO	NO	NO	NO	NO	NO	NO
5 F1429M	NO	NO	NO	NO	NO	NO	NO
6 P1368A	NO	NO	NO	NO	NO	NO	NO
7 V2222D	NO	NO	NO	NO	NO	NO	NO
8 D2313T	NO	NO	NO	NO	NO	NO	NO
9 M1811M	NO	NO	NO	NO	NO	NO	NO
10 M0251V	NO	NO	NO	NO	NO	NO	NO
11 S1458A	NO	NO	NO	NO	NO	NO	NO
12 S2708F	NO	NO	NO	NO	NO	NO	NO
13 C1421F	NO	NO	NO	NO	NO	NO	NO
14 P0606M	NO	NO	NO	NO	NO	NO	NO
15 M1721L	NO	NO	NO	NO	NO	NO	NO
16 D0785A	SI	SI	NO	NO	NO	SI	NO
17 G1408M	NO	NO	NO	NO	NO	NO	NO
18 S2354S	NO	NO	NO	NO	NO	NO	NO
19 A2458S	NO	NO	NO	NO	NO	NO	NO
20 R0335H	NO	NO	NO	NO	NO	NO	NO

Table 2 summarizes the ophthalmological evaluation at T15 time (after 15 days of product use)

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TABLE 3

Volunteer n° T30	Lacrimation	Vasodilatation	Foreign body sensation	Photophobia	Itching	Stinging eyes	Periocular swelling
1 A1643V	NO	NO	NO	NO	NO	NO	NO
2 P0602L	NO	NO	NO	NO	NO	NO	NO
3 C0544S	NO	NO	NO	NO	NO	NO	NO
4 C2582E	NO	NO	NO	NO	NO	NO	NO
5 F1429M	NO	NO	NO	NO	NO	NO	NO
6 P1368A	NO	NO	NO	NO	NO	NO	NO
7 V2222D	NO	NO	NO	NO	NO	NO	NO
8 D2313T	NO	NO	NO	NO	NO	NO	NO
9 M1811M	NO	NO	NO	NO	NO	NO	NO
10 M0251V	NO	NO	NO	NO	NO	NO	NO
11 S1458A	NO	NO	NO	NO	NO	NO	NO
12 S2708F	NO	NO	NO	NO	NO	NO	NO
13 C1421F	NO	NO	NO	NO	NO	NO	NO
14 P0606M	NO	NO	NO	NO	NO	NO	NO
15 M1721L	NO	NO	NO	NO	NO	NO	NO
16 D0785A	SI	SI	NO	NO	NO	SI	NO
17 G1408M	NO	NO	NO	NO	NO	NO	NO
18 S2354S	NO	NO	NO	NO	NO	NO	NO
19 A2458S	NO	NO	NO	NO	NO	NO	NO
20 R0335H	NO	NO	NO	NO	NO	NO	NO

Table 3 summarizes the ophthalmological evaluation at T30 time (after 30 days of product use)

Table 4 and 5 summarize respectively the alterations of eyelid skin and conjunctival mucosa.

TABLE 4

ALTERATIONS OF EYELID			
Volunteer n°	T0	T15	T30
A1643V	0	0	0
P0602L	0	0	0
C0544S	0	0	0
C2582E	0	0	0
F1429M	0	0	0
P1368A	0	0	0
V2222D	0	0	0
D2313T	0	0	0
M1811M	0	0	0
M0251V	0	0	0
S1458A	0	0	0
S2708F	0	0	0
C1421F	0	0	0
P0606M	0	0	0
M1721L	0	0	0
D0785A	0	0	0
G1408M	0	0	0
S2354S	0	0	0
A2458S	0	0	0
R0335H	0	0	0

TABLE 5

ALTERATIONS OF CONJUNCTIVAL MUCOSA			
Volunteer n°	T0	T15	T30
A1643V	0	0	0
P0602L	0	0	0
C0544S	0	0	0
C2582E	0	0	0
F1429M	0	0	0
P1368A	0	0	0
V2222D	0	0	0
D2313T	0	0	0
M1811M	0	0	0
M0251V	0	0	0
S1458A	0	0	0
S2708F	0	0	0
C1421F	0	0	0
P0606M	0	0	0
M1721L	0	0	0
D0785A	0	0	0
G1408M	0	0	0
S2354S	0	0	0
A2458S	0	0	0
R0335H	0	0	0

Volunteer **D0785A** reports, since the first application of the product, a moderate burning accompanied by a slight lacrimation if the product enters the eyes. These discomforts disappear a few minutes after rinsing eyes. The voluntary reports the same discomforts even at T30 but she decided to complete the test.

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CONCLUSIONS

According to the previous results, we can conclude that

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BABY HAPPY HOUR BABY'S SHAMPOO & SHOWER MILK

HAS BEEN OPHTHALMOLOGICALLY TESTED. IT IS SAFE TO BE USED IN THE PERIOCULAR AREA ON SUBJECTS WITH SENSITIVE EYES

During the test period, an episode of discomfort spontaneously disappeared after a few minutes from the application of the product has been reported. Anyway, no enrolled volunteers showed any significant alterations on their eyelid skin or eye mucosa during the study period.

San Martino Siccomario, 10/03/2015

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