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Controlled User Test of the Product "PROWIN EXPRESSION Kajalstift Black"

Ophthalmologic Test

Summary

Study Sponsor.....: **proWIN Winter GmbH**
Zeppelinstraße 8
66557 Illingen
Germany

Performance of Test and Evaluation by.....: Derma Consult Concept GmbH
Hermann-Wandersleb-Ring 4
53121 Bonn
Germany

Supervisor of Study.....: Dr. med. H. O. Vielhaber ophthalmologist
B. Nissen, Manager Derma Consult Concept

Order date.....: 22.06.2015

Test Product.....: The test product, which was coded as follows, was provided by proWIN Winter GmbH:

A. PROWIN EXPRESSION Kajalstift Black
sample delivery 06/2015

Subjects.....: Number of individuals.: 20 (10 wearers of contact lenses)
Sex.....: female
Age range.....: 26 - 59 years (average 40,3)

Test Area.....: Face (eye region)

Application.....: Duration....: 2 weeks
Frequency.: twice daily (to simulate maximum exposure)

Study period.....: July 2015

Performance of Test

Subjects were informed about importance and meaning of the study. Written informed consent was obtained from all the volunteers prior to entry into the trial. Subjects could withdraw from study at any time without giving any reason. The following criteria were used for selection of subjects:

for inclusion in study:
- female
- age >18 years
- clinically healthy
- informed volunteers
- 10 subjects wearing contact lenses (type not standardized) regularly (min. 5 days/week)

for exclusion from study:
- eye diseases
- known allergies to pollen / dust mites
- skin diseases
- pregnancy
- use of corticoids / antiallergics

Day 0:

- Distribution of the test product along with application instructions (to simulate maximum use conditions, test product application was required to be performed twice daily for the entire study period in the morning and reapplication in the afternoon or evening – home application)

Day 14:

- Examination of the eye and eye region by an ophthalmologist

Results

The product was assessed by the subjects very positively. The examination by an ophthalmologist showed, that no subject had subjective or objective eye irritation in form of tears or pain, nor had eyelid irritation been seen after the use of the product for two weeks. No incompatibility (redness, itching) was observed in or reported by any of the volunteers and also no discomfort was reported on.
The examination of the eye ground with the help of a slit-lamp microscope showed that no irritant contact conjunctivitis with chemosis could be observed after the use of the product.