Protocol n. PIT0000216/25_Rev.02 by 30/12/2025 attached to the offer n. 0000116_Rev.02 by 30/12/2025

PLACEBO-CONTROLLED CLINICAL-INSTRUMENTAL EVALUATION OF THE EFFICACY OF A COSMETIC PRODUCT FOR SUBJECTS WITH ATOPIC DERMATITIS

1 – AIM OF THE STUDY	The study is aimed to evaluate the efficacy of a cosmetic product destined to subjects with atopic dermatitis. Double-blind placebo-controlled study. *The trial will be carried out under dermatological control in accordance with the ethical principles applicable to medical research, on the basis of the following trial protocol*.
2 – STUDY PROTOCOL	**2.1. Test subjects** The study will be performed on 80 (88 enrolled*) Caucasian subjects (male or female, no specific repartition), aged over 18 years old, showing clinical signs and skin discomforts of mild to moderate atopic dermatitis on face/body (with skin characterized by dryness, desquamation, erythema, itching symptom - Mild to moderate, SCORAD between 15 and 40). **10% more subjects will be enrolled for a total of 88 subjects.* *According to a predisposed randomization list 40 (44 enrolled) subjects will take the active product and (active group) and 40 subjects (44 enrolled) the placebo (control group).* **2.2. Study design** The study foresees 28 days of product use. Evaluations are performed before (T0), immediately after product application (Timm) and after 7 (T7) and 28 (T28) days of use. **2.3. Monitored parameters** ➢ **Skin moisturization (T0, T7, T28)** The measurement of the skin moisturization is based on the internationally recognized CORNEOMETER® method (Courage+Khazaka, electronic GmbH). This measurement is based on the dielectric constant of water. The probe shows changes of capacitance according to the moisture content of the measuring object. An electric scatter field penetrates the very first layer of the skin and determines the dielectricity. ➢ **Trans Epidermal Water Loss (T0, Timm, T28)** Transepidermal water loss is measured using a Tewameter® TM 300/TM HEX (Courage+Khazaka, electronic GmbH). The measurement is based on the diffusion law, as described by the equation here below: $\frac{dm}{dt} = -D \cdot A \cdot \frac{dp}{dx}$ where: A is the surface in m²; m is the water transported (in g); t is the time (h); D is the diffusion constant (0.0877 g/m(h(mm Hg)); p is the vapor pressure of the atmosphere (mm Hg); s is distance from skin surface to point of measurement (m) The diffusion flow dm/dt indicates the mass of water, which is transported per cm² in a specific period. It is proportional to the area A and the change of concentration per distance (dp/dx). D is the diffusion coefficient of water vapor in the air. The resulting density gradient is measured indirectly by two pairs of sensors (temperature and relative humidity) and is analyzed by a microprocessor. The measuring head of the probe is a narrow hollow cylinder (10 mm diameter and 20 mm height), in order to minimize influences of air turbulence inside the probe. **2.4. Scoring Atopic Dermatitis: (T0, T7, T28)** - *Scoring Atopic Dermatitis (SCORAD):* performed by the dermatologist - *PO-SCORAD (Patient Oriented Scorad):* performed by the subjects.

	2.5. Self-evaluation during application (Timm) The self-scoring assessment concerns the subject's perception during product application. For instance, subjects with atopic dermatitis (AD) may report sensations such as burning, discomfort, or, conversely, a feeling of benefit during the first application. **2.6. Digital pictures (T0, T28)** Digital pictures will be acquired with a digital reflex camera. *5 best cases of ACTIVE side will be included in the final report.* **2.7. Self-assessment questionnaire (T0, T7, T28)** Before product use (T0), after 7 days (T7) of product use and at the end of the study (T28) volunteers are asked to express their personal opinion about the tested product by answering to a specific questionnaire (to be agreed with the customer). **2.8. Quality of life (T0, T28)** *The questionnaire will include specific questions related to a modified quality of life (internal quality of life questionnaire).* **2.9. LC-OCT (T0, T28) on 22 subjects (11 ACTIVE + 11 PLACEBO)** Cross-sectional sectional images will be acquired using Line-field Confocal Optical Coherence Tomography (LC-OCT) technology. Epidermal thickness will be measured and quantified from the obtained images. [1] **Inclusion criteria.** 1. Healthy adult (>18 years old) subjects ; 2. Caucasian ethnicity; 3. Subjects registered with applicable healthcare system; 4. Subjects certifying the truthfulness of the personal data disclosed to the investigator; 5. Subjects able to understand the language used in the investigation centre and the information given by the investigator; 6. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements; 7. The pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) should be stable for at least one month without any changes expected or planned during the study; 8. Commitment not to change the daily routine or the lifestyle. [2] **Non-inclusion criteria**. 1. Subjects with acute or chronic diseases able to interfere with the outcome of the study or that are considered dangerous for the subject or incompatible with the study requirements; 2. Subjects participating or planning to participate in other clinical trials; 3. Subjects deprived of freedom by administrative or legal decision or under guardianship; 4. Subjects not able to be contacted in case of emergency; 5. Subjects admitted to a health or social facility; 6. Subjects planning a hospitalisation during the study; 7. Subjects who participated in a similar study without respecting an adequate washout period; 8. Subjects having an acute, chronic or progressive illness liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements; 9. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator; 10. Subjects having a skin disease or condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements; 11. Subjects that have shown allergies or sensitivity to cosmetic products, drugs, patch or medical devices; 12 Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).
3. SUBJECTS	88 female and male subjects
4. SAMPLES	50 samples of active product (at least 150 ml/g) 50 samples of placebo product (at least 150 ml/g)
5. TIMING	6 weeks for enrollment of subjects 4 weeks of use 3 weeks for data analysis and report

6. DOCUMENTATION	In order to carry out the test, the following documentation is required: - Qualitative INCI formula - Declaration of compliance to the cosmetic regulation 1223/2009 - Way and frequency of use - Self-assessment questionnaire
7. TEST CODE	**H.E.HU.AD.NSO05.020.11.00 with internal QOL**