Clinical Studies

SILC SKIN®

DÉCOLLETTÉ PADS
&
SKIN CLEANSER

50 SUBJECTS \ PAD TEST FOR SKIN IRRITATION AND SKIN SENSITIZATION EVALUATION

OBJECTIVE

To evaluate the effectiveness of a skin care regimen to improve skin conditions based on consumer perception.

STUDY DURATION

Completed within a 2 week period (five (5) day washout period and 1 week product usage).

SUBJECT SELECTION

Panel recruitment will be accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof. Subject selection will be determined in accordance with the criteria listed below.

Number of Subjects: Approximately 8 healthy subjects meeting inclusion/exclusion criteria will be enrolled to complete the study with a minimum of 5 subjects

Sex: Female

Age: 35-65 years of age

Race: Caucasian

Inclusion Criteria:

- Individuals that are in good general health.
- Individuals who are free of any dermatological or systemic disorder, which could interfere with the results, as determined by the Investigator.
- Individuals who will complete a preliminary medical history and HIPAA form.
- Individuals who will be able to read, understand and choose whether or not to sign an informed consent document.
- Individuals who will be able to and agree to cooperate with the Investigator and research staff.

- Individuals that are willing to and able to apply the test product according to the Sponsor supplied instructions and complete the full course of the study.
- Individuals who have not participated in any study involving the same test sites (décolleté) for the past 15 days.
- Individuals with fine lines and wrinkles on their chest (décolleté).
- Individuals who agree to discontinue usage of their current personal care products (e.g. cleansers, lotions, creams, serums) on the test site, with the exception of those provided by BCS, for the duration of the study.
- Individuals who agree not to sunbathe/tan, and agree to avoid sun exposure as much as possible for the duration of the study.

Exclusion Criteria:

- Individuals who have had a history of any acute or chronic disease that would interfere with or increase the risk on study participation.
- Individuals with an active (Rosacea) or chronic skin allergies (atopic dermatitis/ eczema), or had recently treated skin cancer (within the last 12 months).
- Individuals with damaged skin in close proximity to test sites (e.g., sunburn, tattoos, piercings or skin disfigurations).
- Individuals who have any history, which, in the Investigator's opinion, indicates the potential for harm to the subject or places the validity of the study in jeopardy.
- Individuals with a history of immunosuppression/immune deficiency disorders or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.) and/or radiation as determined by study documentation.
- Individuals who indicate that they are pregnant, planning a pregnancy or nursing.
- Individuals who have been medically diagnosed with Diabetes Type I.
- Individuals who have had any medical procedure, such as laser resurfacing, or plastic surgery to the test areas (décolleté) within the last 12 months.
- Individuals who are currently using or during the past 30 days have used, Retin A, or other Rx/OTC Retinyl A, hydroquinone (skin lightening) or other astringent derived products or alpha hydroxyl acid treatments for photo-aging and fine lines/wrinkles.
- Individuals who have a known allergy to medical grade silicone.
- Individuals who have a known history of hypersensitivity to any cosmetics, personal care products and/or fragrances.
- Individuals who are employees of BCS.

PROCEDURE

Subjects will report to the facility a minimum of five (5) days prior to study start.
Prior to beginning any study related activities, subjects will be given an informed consent form, HIPAA form, subject bill of rights, and Code of Conduct form to read.
Once subject has completed reading they will be interviewed, in private, by BioScreen to ensure their understanding of the aforementioned forms and be given the opportunity to ask any study related questions.
Subjects who agree to sign the aforementioned forms will be asked to complete a medical history form. Subjects declining to sign any of the forms will be dismissed from the study.
Subjects will be enrolled on the basis of the subject selection criteria. Subjects failing to meet criteria will be dismissed from the study.
Enrolled subjects will begin the washout period. Subjects will receive SilcSkin Cleanser or a neutral soap (Neutrogena) to use exclusively on their décolleté during the washout period and study duration.
Subjects will be given specific instructions to discontinue usage of their current personal care products (e.g. cleansers, lotions, creams, serums) on the test site for the duration of the study.
Following the five day washout period, subjects will return to the testing facility.
Subjects will be given the test product along with the product use instructions as directed by the Sponsor.
Subjects will be dismissed from the testing facility and informed to return 1 week (± 1 day) post-treatment with the test product. Test products will be weighed and/or evaluated for compliance.
Subjects will be instructed to complete a post-treatment questionnaire.
After completion of the week 1 questionnaire, subjects will be dismissed from the study.

TEST PRODUCT USE INSTRUCTIONS

Using a pearl size of cleanser, lightly lather in hands and apply to décolleté, massaging with gentle, circular motions. Rinse well with lukewarm water and pat dry with a soft towel. Once the skin is completely dry, apply the décolleté pads. Décolleté pads should be worn at night while sleeping for a minimum of 6 hours. Gently remove in the morning.
The pads themselves must be washed at least once during the week of the test (especially if the pads start to not stick as well because of exfoliated skin cells, lint, or debris on the pads). A small pearl amount of cleanser should be applied to the pad and worked into a lather. Rinse

thoroughly with warm water, allow to air dry in a clean area.
Upon arrival at BioScreen Clinical Services (BCS) the test product will be assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested. Each individual sample of the test product will be weighed before and after use by the subject. This information will be recorded on the test product log-in form. Samples will be retained for a period of 30 days beyond submission of final report. Sample disposition will be conducted in compliance with appropriate federal, state and local ordinances.

TEST PRODUCT HANDLING

Test products that have been reviewed and approved for use by the Regulatory and Safety representatives of Calvet Cosmetics will be tested. A sufficient quantity of samples of the above test product to allow for 8 subjects to use for the entire study duration will be received from Calvet Cosmetics prior to start of the study.

SUMMARY OF RESULTS

Under conditions of the study a total of 8 healthy female subjects, 49-64 years of age, completed the clinical study, evaluating the effectiveness of test products: SilcSkin Cleanser and Decollette Pad, to improve skin conditions based on consumer perception.

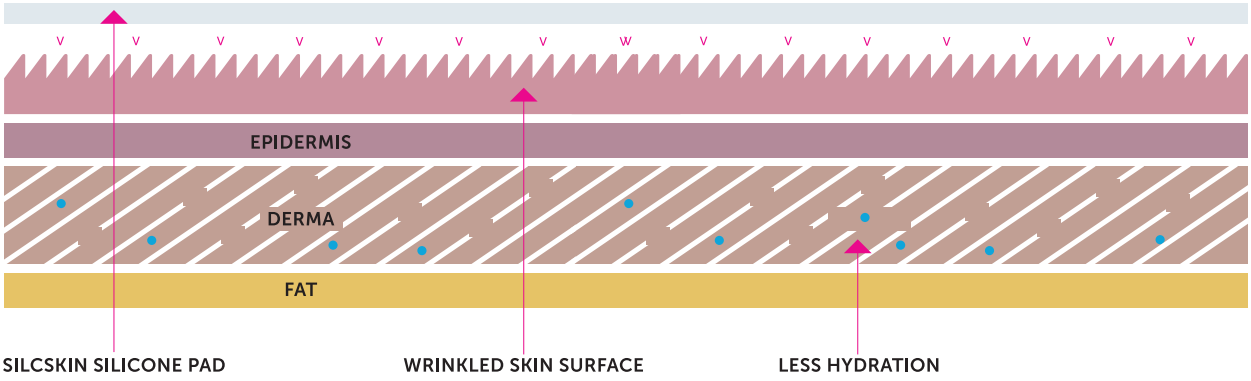
Post Treatment Questionnaire

QUESTION / STATEMENT	
1. There was a visible reduction in fine lines and wrinkles on my chest.	100%
2. My chest lines have softened and are less noticeable than they were yesterday.	100%
3. My skin felt significantly smoother in the morning.	100%
4. I would use this product instead of a medical procedure like Botox, Laser or fillers.	87.5%
5. My chest skin was noticebly more hydrated.	87.5%
6. My chest skin's moisture was replenished overnight.	87.5%
7. I saw an increase in the feel of softness and suppleness.	87.5%
8. This product makes my skin look younger.	100%
9. This product makes my skin look more radiant and youthful.	87.5%
10. My overall skin texture improved.	87.5%
11. This product made the overall appearance of my skin better.	100%
12. The patches were easy to apply.	100%

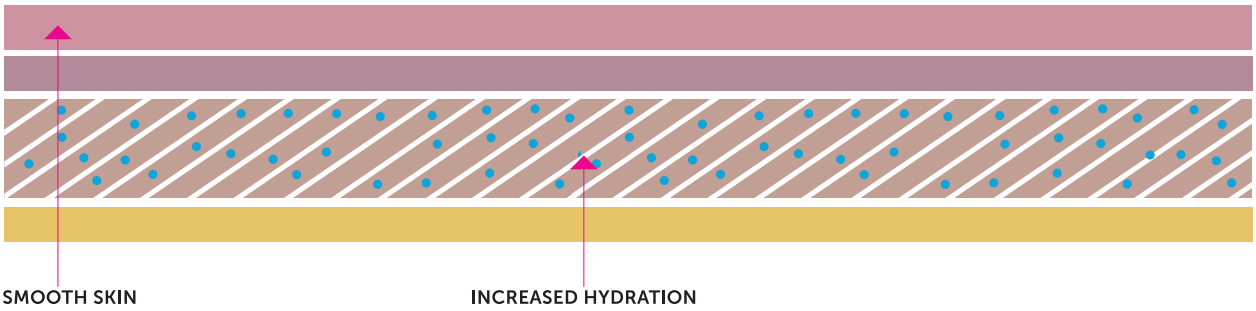
THE SCIENCE BEHIND SILCSKIN

Silicone products have been clinically proven to be one of the most effective at-home scar treatments available for various scar types. These include hypertrophic, keloid, acne, and burn scars, as well as surgical scars, such as those from a cesarean delivery. SilcSkin uses medical-grade silicone sheeting on wrinkles and fine lines. The wrinkles therefore are effectively treated as scars. The silicone used by SilcSkin in the manufacture of their pads has been refined using a platinum curing process. This method of production removes the residue that's typically left behind after silicone has been processed, leaving behind 100% pure silicone.

SKIN SURFACE BEFORE TREATMENT



SKIN SURFACE AFTER TREATMENT



SilcSkin pads work by the science of occlusion. An occlusive prevents evaporative water loss by placing a substance on the skin surface that water cannot penetrate through. When the silicone pads are applied to the treatment area, it creates an environment that super-hydrates the area underneath the pad by replenishing the moisture by water moving from the lower viable epidermal and dermal layers. The skin's natural moisture is increased and plumps the epidermis, reducing the appearance of wrinkles, fine lines, crepey skin, and scars.