

## Summary: Epicutaneous 24 h Patch Test

**Sponsor** Sterisol AB

**Project Manager/Investigator** Dr. med. Swarna Ekanayake-Bohlig, Dermatologist

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**Study Site** proDERM Institute for Applied Dermatological Research,  
Schenefeld/Hamburg, Germany

**proDERM Study No.** 08.0577-05

**Test dates** December 15 to December 18, 2008

**Objective** The aim of this study was to determine the level of primary skin irritation caused by a single application of the test materials for a period of 24 hours. This investigation did not deal with the risk of developing contact allergy - or possible beneficial effects on the skin.

**Test Material**

Code/proDERM	Product/Code/Sponsor
A	Aqua demin. (Negative Control), as is
B	Sodium Dodecyl Sulfate (SDS) (Positive control) / 1 %
C	Shampoo, Extra Sensitive Care (R82-13) / 2 %
D	Conditioner, Extra Sensitive Care (R82-14) / 2 %
E	Shower Cream, Extra Mild Sensitive Cream (R82-12) / 2 %
F	Mild Soap, Extra Sensitive Care (R82-10) / 2 %
G	Body Lotion, Extra Sensitive Care (R82-15) / as is
H	Skin Cream, Extra Sensitive Care (R82-16) / as is
I	Cleansing Cream, Extra Mild Sensitive Cream (R48-4200) / 2 %

**Volunteers Analyzed (Valid Cases)** 20, [100 % with sensitive skin according to self-estimation and/or type IV allergy (except for cosmetic ingredients) and /or atopy]

**Application/  
Application Mode** 75 µl of each test sample were applied with a Finn pipette. Finn Chambers<sup>®</sup>, large, with filter discs (occlusive), backed on Scanpor<sup>®</sup> were used for the test.

**Methods** Test materials were applied to the back of the volunteers for 24 hours using the occlusive epicutaneous patch test system.

Visual scoring was performed 15 minutes after patch removal (i.e. 24 hours after product application) as well as 24 and 48 hours after patch removal (i.e. 48 and 72 hours after product application) using standardized description grades as described below.

This procedure corresponds to the COLIPA guidelines (Cosmetic product test guidelines for the assessment of human skin compatibility, COLIPA, 1995).


**Conclusions** All volunteers (100%) participating in this study had sensitive skin, defined as atopy and/or type IV allergy (except against cosmetic

ingredients) and/or self-estimation. This special panel was elected to test products for sensitive skin in an occlusive patch test.

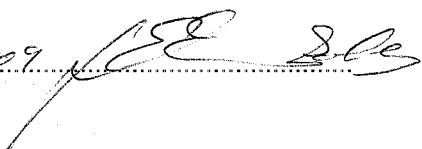
The mean irritation scores of **all test products except products C, E and F** were within the range of the negative control A (Aqua demin.) or very slightly higher at all readings. Therefore, the skin tolerability of these test products with respect to irritancy can be expected to be **"very good"** when used as intended.

The mean irritation scores of **test products C, E and F** were a little bit higher compared to the negative control (Aqua demin.) after 48h and 72h, but lower compared to the mean irritation score of the positive control B (SDS) at all readings. Therefore, the skin tolerability of these test products can be expected to be **"very good to good"** when used as intended.

Dr. med. Walter Wigger-Alberti  
Dermatologist  
- Director Clinical Research/Principal Investigator -

February 12, 2009   
Date / Signature

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