STUDY REPORT

Epicutaneous 24 h Patch Test

Sponsor	Cederroth International AB, Falun, Sweden
Sponsor Contact	Dr. Torsten Hedbom
Study Site	proDERM Institute for Applied Dermatological Research, Schenefeld/Hamburg, Germany
Project Manager/Investigator	Dipl.-Biol. Christiane Röck
proDERM Study No.	11.0320-05
Test Dates	August 29 to September 01, 2011
Report	September 06, 2011

1 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.

2 Project Information

Project Manager/Investigator	Dipl.-Biol. Christiane Röck
Lead Technician	Renate Barre
Data Management/Statistics	Dipl.-Chem. Claudia Lippek
Report	Jennifer Klein, MSc. Biology
Quality Assurance	Dr. rer. nat. Jutta Hofmann

3 Materials and Methods

3.1 Test Materials

The test products were used as supplied by the Sponsor and diluted at the Study Site. Control materials were provided by the Study Site.

Code/proDERM	Product/Code/Sponsor/Concentration
A	Aqua demin. (Negative control) as is
B	Sodium Dodecyl Sulfate (SDS) (Positive control) 1 % (w/w)
C	412629 Tork Foam Soap Mild (+40oC 12 mån.) 2 % (w/w)
D	412740A Tork Foam Soap Mild 2 % (w/w)
E	412629 Tork Foam Soap Mild (ref 12 mån.) 2 % (w/w)
F	412741A Tork Foam Soap Extra Mild 2 % (w/w)
G	521771 Tork Liquid Soap Mild 2 % (w/w)
H	521772 Tork Liquid Soap Luxury Soft 2 % (w/w)
I	521775 Tork Liquid Soap Extra Mild 2 % (w/w)
K	521630 Tork Liquid Soap Mild (Existing) 2 % (w/w)
L	521541 Tork Liquid Soap Extra Mild (Existing) 2 % (w/w)
M	412733 LdB Pumptvål Silk 2 % (w/w)
N	412734 LdB Pumptvål Rich 2 % (w/w)
O	412735 LdB Pumptvål Olive 2 % (w/w)
P	412725 LdB Shower Creme Rich 2 % (w/w)
Q	412726 LdB Shower Vitalizing Silk 2 % (w/w)
R	412727 LdB Shower Spirit 2 % (w/w)
S	412728 LdB Shower Hydra Sensitive Aloe Vera 2 % (w/w)
T	412738 LdB Shower Energizing 2 % (w/w)
U	412736 LdB Deo energizing as is

Date Samples Received	August 18, 2011
Storage Conditions	Room temperature

Application Area	Back
Application Volume	25 µl
Application Mode	The test materials were applied with a Finnpipette
Patch Test System	Occlusive patch test system (Haye's Test Chambers®, HAL Allergy G°mbH)

3.2 Subjects

Subjects Enrolled	22
Complete Data Exclusions	None
Subjects Analyzed (Valid Cases)	22
	(thereof 41 % with sensitive skin according to self-estimation, 0 % with type IV allergy (except for cosmetic ingredients) and 18 % with atopy) (see List of Subjects, Appendix B)
Age	47.7 ± 14.5 years (mean ± standard deviation)
Sex	6 male (27 %) 16 female (73 %)

3.3 Methods

The study has been conducted according to the proDERM Standard Protocol-V07 (05-ECT), the Study Protocol (see Appendix D) and approximating the main principles of GCP.

Day	**1**	**2**	**3**	**4**
Application of Test Materials	X			
Patch Removal (24 h after the last application of test materials)		X		
Visual Evaluation (By a trained evaluator, 15 min, 24h and 48 h after patch removal)		X	X	X

- Test materials were applied to the back of the subjects 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, 1997).

The assessments were performed according to the following scales:

Visual Evaluation

0 = No apparent cutaneous involvement

0.5 = Faint, definite or diffuse erythema (greater than 0, less than 1)

1 = Definite, moderate to severe erythema (possibly slight edema) but skin intact without papules

2 = Severe erythema (possibly moderate edema) may have a few papules, deep fissures, or other defects of skin surface. Moderate-to-severe erythema in the fissures.

3 = Very severe erythema (beet redness) generalized papules or vesicles, and/or other defects of the skin surface extending beyond test site.

4 = Very severe erythema with edema extending beyond test site and vesicles or eschar formations.

Scores were directly entered into a PC system with an appropriate computer program.

3.4 Protocol Violations/Additional Remarks

None

4 Results

A summary of the mean scores and standard deviations at the different reading times is given in Table 1. The mentioned time points (hours) refer to the time after product application.

Table 1: Mean Scores and Standard Deviations of Test Products

Code/ proDERM	24 hours (Day 2)	48 hours (Day 3)	72 hours (Day 4)
A	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
B	0.66 ± 0.39	0.70 ± 0.33	0.48 ± 0.36
C	0.00 ± 0.00	0.07 ± 0.18	0.00 ± 0.00
D	0.02 ± 0.11	0.07 ± 0.18	0.00 ± 0.00
E	0.02 ± 0.11	0.07 ± 0.18	0.00 ± 0.00
F	0.05 ± 0.21	0.00 ± 0.00	0.00 ± 0.00
G	0.05 ± 0.21	0.09 ± 0.20	0.00 ± 0.00
H	0.00 ± 0.00	0.05 ± 0.15	0.00 ± 0.00
I	0.00 ± 0.00	0.02 ± 0.11	0.00 ± 0.00
K	0.05 ± 0.15	0.07 ± 0.18	0.02 ± 0.11
L	0.02 ± 0.11	0.09 ± 0.20	0.05 ± 0.15
M	0.05 ± 0.15	0.07 ± 0.18	0.00 ± 0.00
N	0.02 ± 0.11	0.11 ± 0.21	0.02 ± 0.11
O	0.05 ± 0.15	0.11 ± 0.21	0.02 ± 0.11
P	0.02 ± 0.11	0.05 ± 0.15	0.00 ± 0.00
Q	0.05 ± 0.15	0.05 ± 0.15	0.00 ± 0.00
R	0.02 ± 0.11	0.09 ± 0.20	0.00 ± 0.00
S	0.07 ± 0.18	0.09 ± 0.20	0.02 ± 0.11
T	0.09 ± 0.25	0.09 ± 0.20	0.02 ± 0.11
U	0.05 ± 0.21	0.00 ± 0.00	0.00 ± 0.00

Raw data of all valid subjects are listed in Appendix C. More information about the results is provided in Appendix A (Summary Tables). A list of all subjects that participated in this study is provided in Appendix B (List of Subjects).

5 Conclusions

The mean irritation scores of **all test products C-U** were within the range of the negative control A (Aqua demin.) or 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.

Appendices

Appendix A:	Summary Tables
Appendix B:	List of Subjects
Appendix C:	Raw Data
Appendix D:	Study Protocol

6 Authentication

The signatories confirm that this study was conducted, the analysis performed and the report prepared taking the principles of Good Clinical Practice (GCP) as a guide of reference for this study, and in accordance with the approved protocol(s). The principle requirements of the Declaration of Helsinki were taken into account to protect the rights, safety and well-being of subjects participating in the study. They further confirm that the reported results are a complete and accurate reflection of the clinical research data obtained in this study and based on the statistical analysis to the best of the undersigned's knowledge.

Prof. Dr. med. Klaus-Peter Wilhelm
Dermatologist

September 20, 2011
Date / Signature

Dipl. Bio-Ing. Stephan Bielfeldt
- Director Cosmetic Research -

September 12, 2011
Date / Signature

Dipl.-Biol. Christiane Röck
- Project Manager/Investigator -

September 06, 2011 C. Röck
Date / Signature

The representative signature of the quality assurance unit signifies that quality control measures for completeness and accuracy of the clinical research data, for data analysis and for the reporting of results have been performed by responsible personnel for this study. The quality requirements for the report have been fulfilled to the best of the undersigned's knowledge. This type of study is audited by the quality assurance unit according to the audit schedule.

Dr. rer. nat. Jutta Hofmann
- Head of Quality Assurance/QM -

September 12, 2011 J. Hofmann
Date / Signature

Appendix A

Table: A1 **Mean Values** **Study-No.: 11.0320-05**
Parameter: Visual Score **Parameter-ID: 113**

Prod.	A	B	C	D	E	F	G	H	I	K	L	M	N	O	P	Q	R	S	T	U
Mean/d 2	0.00	0.66	0.00	0.02	0.02	0.05	0.05	0.00	0.00	0.05	0.02	0.05	0.02	0.05	0.02	0.05	0.02	0.07	0.09	0.05
Mean/d 3	0.00	0.70	0.07	0.07	0.07	0.00	0.09	0.05	0.02	0.07	0.09	0.07	0.11	0.11	0.05	0.05	0.09	0.09	0.09	0.00
Mean/d 4	0.00	0.48	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.02	0.05	0.00	0.02	0.02	0.00	0.00	0.00	0.02	0.02	0.00

Table: A2 **Study-No.: 11.0320-05**
Parameter: Visual Score: Mean Score **Formula Typ: 5**

Prod.	A	B	C	D	E	F	G	H	I	K	L	M	N	O	P	Q	R	S	T	U
Mean/d2+d3+d4	0.00	0.61	0.02	0.03	0.03	0.02	0.05	0.02	0.01	0.05	0.05	0.04	0.05	0.06	0.02	0.03	0.04	0.06	0.07	0.02

Table: A3 **day 2** **Study-No.: 11.0320-05**
Number of Reactions: Visual Score **Parameter-ID: 37971**

Score \ Prod.	A	B	C	D	E	F	G	H	I	K	L	M	N	O	P	Q	R	S	T	U
0	22	4	22	21	21	21	21	22	22	20	21	20	21	20	21	20	21	19	19	21
0.5	0	7	0	1	1	0	0	0	0	2	1	2	1	2	1	2	1	3	2	0
1	0	11	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	1	1
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
n	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22

Table: A4 **day 3** **Study-No.: 11.0320-05**
Number of Reactions: Visual Score **Parameter-ID: 37973**

Score \ Prod.	A	B	C	D	E	F	G	H	I	K	L	M	N	O	P	Q	R	S	T	U
0	22	2	19	19	19	22	18	20	21	19	18	19	17	17	20	20	18	18	18	22
0.5	0	9	3	3	3	0	4	2	1	3	4	3	5	5	2	2	4	4	4	0
1	0	11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
n	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22

Table: A5 **day 4** **Study-No.: 11.0320-05**
Number of Reactions: Visual Score **Parameter-ID: 37974**

Score \ Prod.	A	B	C	D	E	F	G	H	I	K	L	M	N	O	P	Q	R	S	T	U
0	22	6	22	22	22	22	22	22	22	21	20	22	21	21	22	22	22	21	21	22
0.5	0	11	0	0	0	0	0	0	0	1	2	0	1	1	0	0	0	1	1	0
1	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
n	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22

Appendix B

Subject No.	Status	ID	Initials	Sex	Age	Atopy	Typ IV Allergies	Sensitive Skin
1	c	16786	N.S.	f	34	n	n	y
2	c	19474	N.P.	f	25	y	n	y
3	c	9551	C.G.	f	41	y	n	y
4	c	17194	A.S.	m	36	n	n	n
5	c	17260	M.F.	f	62	n	n	n
6	c	10545	M.W.	m	51	y	n	y
7	c	17195	B.S.	f	34	n	n	n
8	c	8292	E.F.	f	48	n	n	y
9	c	7532	A.B.	m	55	n	n	n
10	c	15950	B.S.	f	47	n	n	n
11	c	6762	K.T.	f	66	n	n	y
12	c	6789	A.T.	m	67	n	n	n
13	c	11293	S.N.	f	54	n	n	n
14	c	9785	H.J.	m	21	y	n	y
15	c	12933	J.J.	f	56	n	n	n
16	c	11803	Z.Y.	f	26	n	n	y
17	c	3130	A.P.	f	49	n	n	n
18	c	214	C.B.	f	63	n	n	n
19	c	13413	H.v.	m	55	n	n	n
20	c	15512	B.G.	f	44	n	n	y
21	c	7005	E.B.	f	75	n	n	n
22	c	8596	S.L.	f	41	n	n	n

c = completed as intended according to study protocol (PP)

Appendix C

Table: C1									**day 2**										**Study-No.: 11.0320-05**	
Parameter: Visual Score																			**Parameter-ID: 37971**	
Pan. # \ Prod.	A	B	C	D	E	F	G	H	I	K	L	M	N	O	P	Q	R	S	T	U
1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0
2	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	1	0	0	0	1	1	0	0	0	0	0.5	0	0.5	0	0.5	0	0.5	1	1
5	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0.5	0	0	0	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0	0
10	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0.5	0	0.5	0.5	0	0	0	0	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0
Mean	**0.00**	**0.66**	**0.00**	**0.02**	**0.02**	**0.05**	**0.05**	**0.00**	**0.00**	**0.05**	**0.02**	**0.05**	**0.02**	**0.05**	**0.02**	**0.05**	**0.02**	**0.07**	**0.09**	**0.05**
SD	0.00	0.39	0.00	0.11	0.11	0.21	0.21	0.00	0.00	0.15	0.11	0.15	0.11	0.15	0.11	0.15	0.11	0.18	0.25	0.21
n	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22

Table: C2									**day 3**										**Study-No.: 11.0320-05**	
Parameter: Visual Score																			**Parameter-ID: 37973**	
Pan. # \ Prod.	A	B	C	D	E	F	G	H	I	K	L	M	N	O	P	Q	R	S	T	U
1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	1	0	0	0	0	0	0	0	0	0	0	0.5	0.5	0	0	0	0.5	0.5	0
5	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	1	0.5	0.5	0.5	0	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0
8	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	1	0	0	0	0	0	0	0	0.5	0.5	0	0	0	0	0	0	0	0	0
10	0	1	0	0	0	0	0	0	0	0	0	0	0.5	0.5	0	0	0	0	0	0
11	0	1	0	0	0	0	0	0	0	0	0.5	0.5	0.5	0.5	0	0	0	0	0	0
12	0	1	0	0	0.5	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.5	0	0	0
19	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0.5	0.5	0.5	0	0	0.5	0.5	0	0	0	0	0	0	0	0	0.5	0.5	0.5	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0.5	0.5	0.5	0.5	0	0.5	0	0	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0
Mean	**0.00**	**0.70**	**0.07**	**0.07**	**0.07**	**0.00**	**0.09**	**0.05**	**0.02**	**0.07**	**0.09**	**0.07**	**0.11**	**0.11**	**0.05**	**0.05**	**0.09**	**0.09**	**0.09**	**0.00**
SD	0.00	0.33	0.18	0.18	0.18	0.00	0.20	0.15	0.11	0.18	0.20	0.18	0.21	0.21	0.15	0.15	0.20	0.20	0.20	0.00
n	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22

Table: C3									**day 4**										**Study-No.: 11.0320-05**	
Parameter: Visual Score																			**Parameter-ID: 37974**	
Pan. # \ Prod.	A	B	C	D	E	F	G	H	I	K	L	M	N	O	P	Q	R	S	T	U
1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	1	0	0	0	0	0	0	0	0	0	0	0.5	0.5	0	0	0	0.5	0.5	0
5	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0.5	0	0	0	0	0	0	0	0.5	0.5	0	0	0	0	0	0	0	0	0
10	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	1	0	0	0	0	0	0	0	0	0.5	0	0	0	0	0	0	0	0	0
12	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0.5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mean	**0.00**	**0.48**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.02**	**0.05**	**0.00**	**0.02**	**0.02**	**0.00**	**0.00**	**0.00**	**0.02**	**0.02**	**0.00**
SD	0.00	0.36	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.11	0.15	0.00	0.11	0.11	0.00	0.00	0.00	0.11	0.11	0.00
n	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22	22

Appendix D

STUDY PROTOCOL

Epicutaneous 24 h Patch Test (05-ECT) according to Standard Protocol-V07

Further details of the test procedure not described in this Study Protocol are explained in the Standard Protocol-V07

Sponsor	Cederroth International AB, Falun, Sweden
Sponsor Contact	Dr. Torsten Hedbom
Study Site	proDERM Institute for Applied Dermatological Research, Schenefeld/Hamburg, Germany
Dermatologist	Prof. Dr. med. Klaus-Peter Wilhelm, Dermatologist
Director Cosmetic Research	Dipl. Bio-Ing. Stephan Bielfeldt
Project Manager/ Investigator	Dipl.-Biol. Christiane Röck
proDERM Study-No.	11.0320-05
Test Dates	August 29 to September 01, 2011
Final Report	Approximately 3 weeks after completion of the study.

Test Materials

Code/ proDERM	Product/Code/Sponsor	Concentration	Dilution to be done by: (Please tick)	
			pro-DERM	Spon-sor
A	Aqua demin. (Negative control)	as is	-	-
B	Sodium Dodecyl Sulfate (SDS) (Positive control)	1 % (w/w)	X	-
C	412629 Tork Foam Soap Mild (+40oC 12 mån.)	2 % (w/w)	X	-
D	412740A Tork Foam Soap Mild	2% (w/w)	X	-
E	412672 Tork Foam Soap Extra Mild (+40oC 9,5 mån.)	2% (w/w)	X	-
F	412741A Tork Foam Soap Extra Mild	2% (w/w)	X	-
G	521771 Tork Liquid Soap Mild	2% (w/w)	X	-
H	521772 Tork Liquid Soap Luxury Soft	2% (w/w)	X	-
I	521775 Tork Liquid Soap Extra Mild	2% (w/w)	X	-

K	521630 Tork Liquid Soap Mild (Existing)	2% (w/w)	X	-
L	521541 Tork Liquid Soap Extra Mild (Existing)	2% (w/w)	X	-
M	412733 LdB Pumptvål Silk	2% (w/w)	X	-
N	412734 LdB Pumptvål Rich	2% (w/w)	X	-
O	412735 LdB Pumptvål Olive	2% (w/w)	X	-
P	412725 LdB Shower Creme Rich	2% (w/w)	X	-
Q	412726 LdB Shower Vitalizing Silk	2% (w/w)	X	-
R	412727 LdB Shower Spirit	2% (w/w)	X	-
S	412728 LdB Shower Hydra Sensitive Aloe Vera	2% (w/w)	X	-
T	412738 LdB Shower Energizing	2% (w/w)	X	-
U	412736 LdB Deo energizing	as is	-	-

Application Volume

25 µl

Patch Test System

Haye's Test Chamber®, HAL (occlusive)

Subjects

A minimum of 22 subjects will be recruited for this study so that at least 20 subjects are expected to finish this study.

Quality Assurance

The study will be conducted, the analysis performed and the report prepared approximating the main principles of Good Clinical Practice (GCP), and in accordance with relevant national regulations, and approved protocol(s). The principle requirements of the Declaration of Helsinki will be taken into account to protect the rights, safety and well-being of subjects participating in the study.

An independent quality assurance unit will be engaged to audit clinical research studies to identify, evaluate and communicate the state of compliance with applicable protocol(s), and the quality system of proDERM. The audit schedule approved by management will ensure that study specific and system audits will be performed at regular intervals. Objective evidence pertaining to the correct conduct of studies, the performance of quality control measures for completeness and accuracy of clinical research data, data analysis, and reporting of results will be given and reported to management and to the investigator, as appropriate.

Sponsor Inspections/ Audits

The Sponsor may, upon appointment, visit the Study Center at any time during and after the study.

Amendments/ Deviations

None

proDERM

Protocol approved:

Date:

Dr. Torsten Hedbom
Cederroth International AB

Date: August 20, 2011

Dipl.-Biol. Christiane Röck
- Project Manager/Investigator -
proDERM

proDERM

Innocuousness Certification for Test Materials

(Not applicable, if an appropriate document will be sent to proDERM)

We herewith confirm that all test materials including references and control materials conform to European Cosmetic Regulation (in the case of cosmetics), or contain only food products in legally accepted quantities (in the case of dietary supplements).

We further confirm that we have sufficient evidence for the innocuousness of the test materials, of the dietary security (for food supplements) and that the test materials present no foreseeable health risks for the panelists taking part in the study under the conditions as defined in the study protocol and its amendments.

Date:

.....

Name / Cederroth International AB

R&D Manager

Position