E 2P

Institut für Angewandte Dermatologische Forschung

Report

CLINICAL STUDY TO EVALUATE THE ANTI-DANDRUFF EFFICACY OF SHAMPOOS

***proDERM* study number: 99.110-11**
***proDERM* order number: 200480**

Study site:	*proDERM* Institut für Angewandte Dermatologische Forschung GmbH, Schenefeld/Hamburg, Germany
Sponsor:	Clariant GmbH, Frankfurt am Main
Sponsor Contact:	Dr. A. Turowski
Investigator:	Priv.-Doz. Dr. med. K.-P. Wilhelm, Schenefeld/Hamburg
Study date:	November 02 to December 14, 1999
Report date:	February 04, 2000

II. Authentication

I, the undersigned confirm with my signature that this study was performed under my supervision according to the procedures herein described. The principles of Good Clinical Practice (GCP) were taken as a guide of reference for the conduct of this study.

February 07, 2000
Date

K.-P. Wilhelm, MD
Dermatologist
Principal Investigator

This report constitutes a true and faithful account of the procedures adopted and the results obtained in this study.

February 4, 2000
Date

K. Articus
Report

This final report as well as the study protocol, the study procedures and data obtained were regularly inspected by the quality assurance unit.

February 7, 2000
Date

W. Havemeister
Quality Assurance

II. Objective

Quantification of the anti-dandruff effect of 2 anti-dandruff shampoo preparations.

III. Project information

Conduct of Study: K. Articus

Technical Assistance: P. Jacobs

Test materials:

proDERM Code	active ingredient
•	none (Placebo)
A	0.3 % Octopyrox
B	0.3 % Zinkpyrithion

Date samples received: November 01,1999

Storage conditions: Room temperature

IV. Methods and Results

Test panel

51 panelists from Schenefeld/Hamburg and its neighboring communities took part after signing a written informed consent form (24 male and 27 female panelists, mean age ± standard deviation: 44.6 ± 12.8 (see Appendix C)).

Methods

The test was conducted in accordance to the protocol synopsis (see Appendix E). Briefly, the panelists used a placebo shampoo (without any active anti-dandruff ingredient) for two weeks. Afterwards each panelist used either product A or product B for a period of 4 weeks. Usage frequency was open to the panelist.

Before and after the 4 week usage period, scalp scales were combed out of the panelists' hair in a standardized fashion for later quantification (see below). Additionally panelists were asked for their opinion on the anti-dandruff effect of the shampoo and were questioned for subjective symptoms (itching, burning).

Quantification of scalp scales

Gravimetric Determination

Scalp scales were measured by weight (Scaltec SBC 31, Heiligenstadt, Germany, scale interval: 0.0001 g).

Image analysis

Scalp scales were evenly spread on a black cardboard of approx. 3 x 3 cm^2 and then recorded with a CCD-camera. The camera image was analyzed using the program NIH image (version 1.62, U.S. National Institute of Health). Size, number and area of scalp scales were determined. Scalp scales were classified into 11 categories and the number of scalp scales in each category was counted.

Results

Gravimetric Determination

The results of the gravimetric determination are listed in tables 4a & 4b (Appendix B). Both products resulted in a significant decrease in weight. For product A the weight decreased from 5.52 to 2.33 mg, for product B from 9.57 to 2.11 mg. The high baseline value for product B resulted from three panelists with extremely high amounts of scalp scales (#15, #30, and #43). Additionally in both groups panelists were found were the placebo treatment alone reduced the number of scalp scales to zero.

Image analysis

The results of the image analysis are listed in tables 1a & 1b, 2a & 2b, 3a & 3b (Appendix B). The area covered with scalp scales was decreased significantly by both products. For product A the area decreased from 306.87 to 44.27 mm^2, for product B from 277.80 to 29.01 mm^2.

The distribution of scalp scale sizes (as shown in figure 1a & 1b) demonstrates, that the number of smaller scalp scales (categories I to III) was decreased by both products, whereas the number of medium to larger scalp scales (categories IV to XI) remained constant.

Subjective evaluation

The results of the subjective evaluation are listed in the following tables (page 5). For both products an improvement of scalp scale related symptoms was noted.

Itching	Product A		Product B	
	before	after	before	after
	4 weeks of application		4 weeks of application	
none	10	16	6	17
low	7	6	4	4
moderate	5	2	7	2
strong	3	1	7	2

Burning	Product A		Product B	
	before	after	before	after
	4 weeks of application		4 weeks of application	
none	24	21	21	22
low	0	3	1	3
moderate	0	0	1	0
strong	0	0	0	0

Anti-dandruff effect	Product A		Product B	
	before	after	before	after
	4 weeks of application		4 weeks of application	
none	7	3	9	3
low	3	14	0	10
moderate	4	8	8	5
strong	2	0	1	7

V. Summary

For both products an anti-dandruff effect was determined. With the aid of image analysis it was found that predominantly the number of small scalp scales was reduced whereas medium to large sized scalp scales remained unaffected.

Appendices

A Figures
B Tables
C Panelist list
D Statistic
E Protocol synopsis

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Appendix A

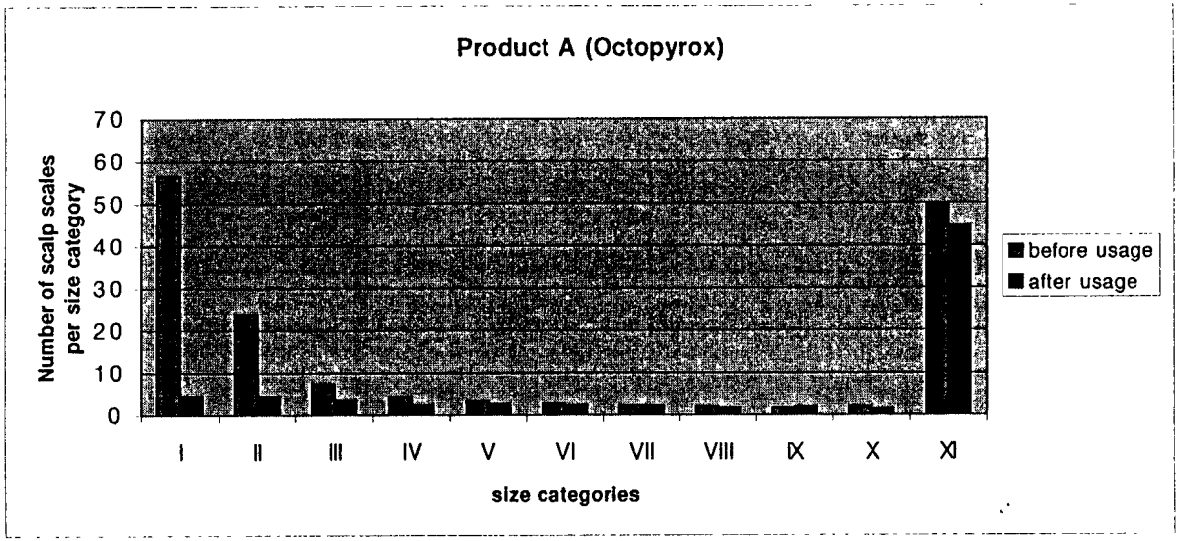

figure 1a

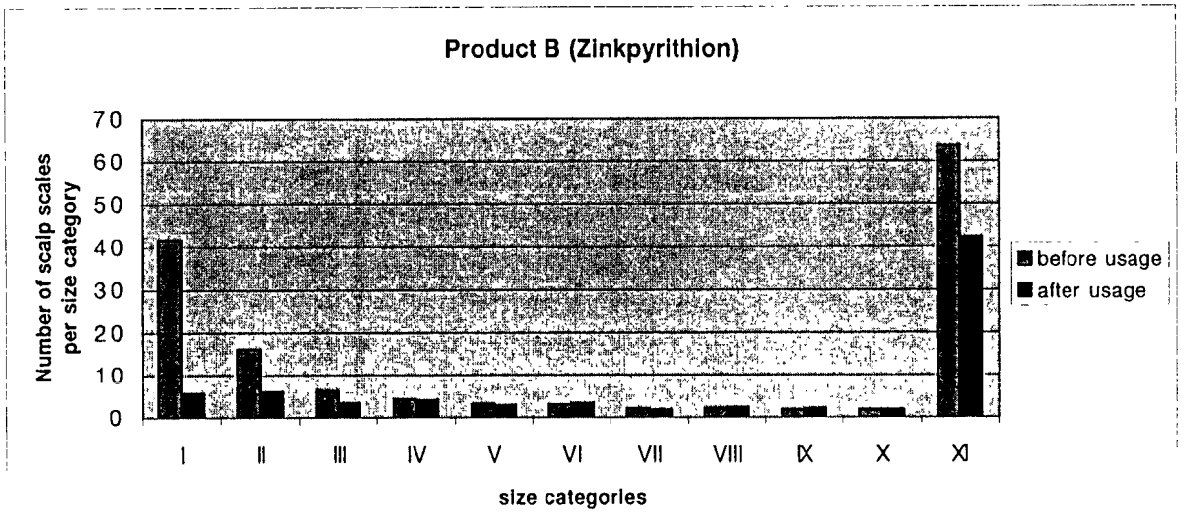

figure 1b

Category I up to 0.0025 II up to 0.0075 III up to 0.0125 IV up to 0 0175 V up to 0.0225 VI up to 0.0275 VII up to 0.0325 VIII up to 0.0375 IX up to 0.0425 X up to 0 0475 XI above 0 05 (all values in squaremillimeter)

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Appendix B

Number of scalp scales per size category / Product A baseline values											
Panelist	I	II	III	IV	V	VI	VII	VIII	IX	X	XI
2	11	8	10	7	12	9	6	6	5	5	177
4	140	70	15	7	3	2	1	1	4	0	13
5	0	0	0	0	0	0	0	0	0	0	0
6	3	3	0	4	2	2	3	3	3	2	131
8	160	63	12	4	5	2	0	1	2	1	6
9	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0
14	7	4	7	3	5	2	6	3	3	2	110
16	4	6	8	8	4	10	4	5	3	1	96
17	2	4	5	2	0	3	0	1	1	1	146
18	0	0	0	0	0	0	0	0	0	0	0
19	145	59	12	5	5	1	6	2	0	1	20
22	148	60	15	6	6	3	2	1	0	3	12
27	2	4	5	1	7	0	1	1	4	2	179
28	134	66	17	7	7	1	4	0	1	1	18
31	148	51	9	6	1	2	1	2	1	2	33
32	0	0	0	0	0	0	0	0	0	0	1
33	8	7	10	10	3	6	5	9	4	8	151
35	1	9	1	1	2	1	2	2	0	1	10
37	165	58	14	5	2	2	0	1	0	1	8
38	3	5	2	5	6	5	1	1	0	2	13
39	4	5	13	4	6	8	5	3	4	3	118
40	147	58	11	9	3	3	3	3	0	3	16
42	81	21	1	7	3	1	0	1	0	5	9
48	3	2	5	2	0	1	3	0	0	1	9
51	153	59	16	7	2	1	1	1	2	0	14
mean	56.5	23.7	7.2	4.2	3.2	2.5	2.1	1.8	1.4	1.7	49.6
sd	70.5	27.7	5.9	3.1	3.0	2.8	2.2	2.1	1.7	1.9	62.9

Table 1a

Number of scalp scales per size category / Product A end values											
Panelist	I	II	III	IV	V	VI	VII	VIII	IX	X	XI
2	10	15	8	8	4	8	9	9	6	6	143
4	7	7	8	2	8	7	6	2	8	8	178
5	19	12	10	2	0	6	5	3	1	1	102
6	3	2	4	2	1	1	2	2	1	2	109
8	9	2	5	5	5	4	2	1	2	0	14
9	2	3	3	0	1	2	2	0	0	0	6
10	0	0	0	0	0	0	0	0	0	0	0
14	2	6	1	3	3	2	2	0	1	3	97
16	3	3	1	3	2	1	0	0	1	0	10
17	8	7	10	3	7	5	3	5	5	4	158
18	0	0	0	0	0	0	0	0	0	0	0
19	9	3	5	2	2	2	2	2	2	0	61
22	8	12	16	6	7	7	6	0	5	5	95
27	3	6	5	1	2	1	2	2	0	1	19
28	1	4	2	2	1	1	2	1	1	0	8
31	7	6	0	2	4	2	1	0	1	2	27
32	9	8	4	5	4	3	6	5	6	1	70
33	4	9	3	4	1	2	2	2	2	0	46
35	1	2	0	2	1	0	1	2	1	0	4
37	0	1	1	1	0	0	0	0	0	0	2
38	3	0	1	2	0	1	0	0	2	0	5
39	2	1	0	0	1	0	1	1	0	0	1
40	0	0	1	0	0	0	0	0	0	0	0
42	4	2	0	1	1	1	0	0	2	0	4
48	0	1	2	0	0	0	0	1	0	0	3
51	0	0	0	1	0	2	0	0	0	0	0
mean	4.4	4.3	3.5	2.2	2.5	2.2	2.1	1.5	1.8	1.3	44.7
sd	4.5	4.2	4.1	2.0	2.7	2.4	2.4	2.1	2.3	2.2	55.9

Table 1b

Category: I up to 0.0025 II up to 0.0075 III up to 0.0125 IV up to 0.0175 V up to 0.0225 VI up to 0.0275 VII up to 0.0325 VIII up to 0.0375 IX up to 0.0425 X up to 0.0475 XI above 0.05 (all values in squaremillimeter)

Number of scalp scales per size category / Product B baseline values											
Panelist	I	II	III	IV	V	VI	VII	VIII	IX	X	XI
1	18	14	10	12	11	3	4	2	2	5	158
3	155	50	17	9	4	6	0	2	1	0	12
7	54	23	7	3	4	1	0	1	2	0	76
11	2	0	2	2	0	0	0	1	0	2	12
12	154	66	13	3	2	1	2	0	1	0	14
13	87	22	3	2	2	1	1	1	1	0	11
15	176	42	12	5	3	1	3	0	2	0	12
20	6	6	9	4	5	6	2	2	3	2	182
21	6	5	5	5	3	3	3	5	0	2	50
23	8	9	8	7	6	5	7	7	2	5	169
24	4	7	7	3	0	1	1	2	1	3	120
25	166	57	8	7	5	4	1	1	0	1	6
26	4	4	2	0	2	2	0	4	0	3	54
29	9	9	9	11	6	10	9	4	5	5	111
30	3	1	3	4	1	2	0	3	4	1	69
34	8	4	6	5	6	7	4	3	1	2	102
36	0	0	0	0	0	0	0	0	0	0	0
41	2	4	3	2	4	2	2	4	2	1	66
43	1	7	5	2	3	10	3	2	6	3	116
44	5	5	1	4	3	3	1	2	0	2	122
45	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0	1
47	10	12	10	6	7	5	4	3	5	2	54
49	160	53	16	9	3	1	2	0	0	0	12
50	4	5	3	3	0	1	1	2	3	2	59
mean	41.7	16.2	6.4	4.3	3.2	3.0	2.0	2.0	1.6	1.6	63.5
sd	64.5	20.3	4.9	3.4	2.7	2.9	2.3	1.8	1.8	1.7	57.3

Table 2a

Number of scalp scales per size category / Product B end values											
Panelist	I	II	III	IV	V	VI	VII	VIII	IX	X	XI
1	7	18	15	15	7	11	4	8	5	10	114
3	3	7	5	12	7	8	9	8	4	5	91
7	3	4	7	5	2	3	0	0	0	1	106
11	1	2	1	0	0	1	0	1	0	0	5
12	9	3	7	7	1	10	3	4	7	1	109
13	2	2	2	6	4	2	0	1	2	0	28
15	12	12	5	4	5	8	4	6	7	3	100
20	10	8	8	4	8	5	7	4	2	6	87
21	1	1	2	2	0	2	1	3	0	0	8
23	4	4	1	2	1	3	0	1	0	2	25
24	0	0	0	0	0	0	0	0	0	0	0
25	3	4	3	6	2	6	2	1	5	1	56
26	7	5	4	2	2	2	0	1	1	0	23
29	0	7	0	1	1	1	0	0	2	0	22
30	6	2	1	4	1	0	0	0	1	0	10
34	8	8	1	8	4	4	2	2	1	0	21
36	0	0	0	0	0	0	1	0	0	0	2
41	6	10	2	3	2	2	2	3	3	2	43
43	5	4	2	1	2	2	1	0	2	3	56
44	13	5	4	6	5	4	4	5	1	5	45
45	0	1	0	0	0	0	0	0	0	0	1
46	35	27	7	9	11	6	5	7	5	4	63
47	0	0	0	0	0	0	0	0	0	0	0
49	6	17	8	4	3	1	0	1	3	2	34
50	1	3	0	2	0	1	0	1	1	0	3
mean	5.7	6.2	3.4	4.1	2.7	3.3	1.8	2.3	2.1	1.8	42.1
sd	7.2	6.5	3.7	3.9	3.0	3.2	2.5	2.7	2.2	2.5	38.7

Table 2b

Category: I up to 0.0025 II up to 0.0075 III up to 0.0125 IV up to 0.0175 V up to 0.0225 VI up to 0.0275 VII up to 0.0325 VIII up to 0.0375 IX up to 0.0425 X up to 0.0475 XI above 0.05 (all values in squaremillimeter)

Area covered by scalp scales (baseline value [mm²])			
Panelist	Product A	Panelist	Product B
2	241.8	1	76.9
4	831.5	3	648.0
5	213.2	7	448.7
6	247.4	11	2.0
8	595.1	12	696.1
9	0.0	13	796.3
10	0.0	15	818.0
14	29.6	20	177.6
16	25.6	21	15.0
17	98.7	23	84.5
18	0.0	24	104.0
19	623.0	25	820.6
22	731.8	26	70.9
27	199.6	29	40.8
28	391.9	30	548.6
31	365.5	34	35.4
32	739.0	36	0.0
33	79.7	41	18.7
35	1.9	43	54.3
37	793.5	44	75.8
38	2.9	45	0.0
39	69.9	46	681.0
40	530.2	47	13.5
42	673.4	49	686.9
48	1.4	50	31.3
51	491.9		
Mean	306.87		277.80
SD	295.83		320.37

Table 3a

Area covered by scalp scales (end value [mm²])			
Panelist	Product A	Panelist	Product B
2	206.8	1	37.6
4	110.6	3	32.2
5	254.4	7	155.6
6	149.0	11	2.5
8	2.9	12	243.9
9	1.5	13	7.1
10	0.0	15	83.0
14	84.5	20	21.7
16	1.1	21	3.5
17	201.3	23	5.8
18	0.0	24	0.0
19	61.0	25	12.3
22	36.8	26	11.0
27	3.0	29	4.3
28	1.3	30	1.9
31	10.2	34	3.0
32	12.1	36	0.8
33	10.0	41	12.9
35	10.9	43	25.1
37	1.1	44	25.6
38	1.1	45	0.1
39	0.2	46	21.4
40	0.0	47	0.0
42	0.7	49	13.1
48	0.3	50	0.9
51	0.1		
Mean	44.27		29.01
SD	75.92		55.89

Table 3b

Scalp scale weight (baseline value [mg])			
Panelist	Product A	Panelist	Product B
2	15.7	1	6.9
4	11.6	3	1.8
5	13.6	7	19.0
6	12.0	11	0.2
8	11.4	12	13.5
9	0.0	13	11.3
10	0.0	15	49.1
14	3.4	20	27.1
16	3.2	21	1.1
17	1.8	23	9.8
18	0.0	24	3.8
19	15.3	25	0.6
22	2.5	26	6.2
27	7.9	29	2.3
28	0.5	30	32.1
31	8.6	34	0.7
32	1.1	36	0.0
33	4.1	41	1.9
35	0.3	43	30.0
37	1.3	44	3.4
38	1.7	45	0.0
39	8.5	46	13.4
40	1.2	47	0.7
42	17.0	49	0.5
48	0.1	50	3.8
51	0.5		
Mean	5.52		9.57
SD	5.79		12.71

Table 4a

Scalp scale weight (end value [mg])			
Panelist	Product A	Panelist	Product B
2	8.4	1	1.8
4	6.1	3	1.0
5	9.8	7	4.5
6	10.4	11	0.3
8	0.5	12	14.3
9	0.1	13	0.3
10	0.0	15	3.6
14	3.9	20	1.5
16	0.2	21	3.0
17	6.8	23	0.5
18	0.0	24	0.0
19	3.0	25	0.8
22	3.6	26	1.1
27	1.0	29	0.4
28	0.3	30	1.2
31	1.3	34	1.4
32	1.8	36	0.1
33	1.5	41	2.3
35	0.1	43	2.4
37	0.1	44	3.6
38	0.2	45	0.0
39	0.1	46	6.4
40	0.2	47	0.0
42	0.2	49	1.9
48	0.7	50	0.3
51	0.3		
Mean	2.33		2.11
SD	3.25		3.00

Table 4b

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Appendix C

Panelist No.	Status	ID	Initials	Sex	Age
1	c	3741	S.H.	f	27
2	c	3818	T.H.	m	36
3	c	3979	B.K.	f	60
4	c	2562	W.K.	m	56
5	c	1956	W.R.	m	67
6	c	2415	S.G.	m	38
7	c	2844	H.B.	m	61
8	c	3830	D.K.	f	37
9	c	3550	E.D.	f	34
10	c	3485	E.B.	f	57
11	c	3994	N.W.	f	28
12	c	4151	R.J.	f	40
13	c	2755	H.S.	m	71
14	c	3808	R.K.	m	58
15	c	3703	R.R.	m	56
16	c	3702	R.R.	f	67
17	c	4181	A.S.	f	44
18	c	391	T.K.	m	35
19	c	2938	B.G.	m	41
20	c	3126	R.T.	m	56
21	c	2571	R.S.	m	65
22	c	2640	H.V.	f	30
23	c	2346	B.D.	m	38
24	c	3755	F.K.	m	33
25	c	2200	S.D.	f	32
26	c	2861	P.H.	f	36
27	c	3020	W.W.	m	59
28	c	2625	D.O.	m	60
29	c	2765	H.W.	m	40
30	c	4140	A.O.	f	34
31	c	170	T.B.	m	31
32	c	2133	H.M.	m	59
33	c	1961	G.J.	m	63
34	c	2233	A.S.	f	38
35	c	3144	S.F.	f	43
36	c	3600	B.K.	f	25
37	c	3583	M.B.	f	27
38	c	3920	B.H.	f	24
39	c	221	U.M.	m	37
40	c	3090	L.C.	f	48
41	c	4084	M.R.	f	48
42	c	3129	C.H.	f	44
43	c	4007	R.N.	m	35
44	c	4008	A.N.	f	33

c = completed as intended according to study protocol

List of Panelists

Panelist No.	Status	ID	Initials	Sex	Age
45	c	2203	M.P.	f	43
46	c	3668	J.S.	m	36
47	c	3598	E.F.	f	49
48	c	3780	R.B.	m	60
49	c	2802	K.J.	f	39
50	c	2183	G.H.	f	43
51	c	2579	M.J.	f	56

c = completed as intended according to study protocol

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Appendix D

Descriptive Statistics

	Mean	Std. Dev.	Std. Error	Count	Minimum	Maximum	# Missing
Weight A t0	5.515	5.786	1.135	26	0.000	17.000	0
Weight A t1	2.331	3.246	.637	26	0.000	10.400	0
Weight B t0	9.568	12.707	2.541	25	0.000	49.100	1
Weight B t1	2.108	3.004	.601	25	0.000	14.300	1
Area A t0	320.685	296.081	58.066	26	0.000	831.500	0
Area A t1	44.265	75.918	14.889	26	0.000	254.400	0
Area B t0	277.796	320.382	64.076	25	0.000	820.600	1
Area B t1	29.012	55.885	11.177	25	0.000	243.900	1

Wilcoxon Signed Rank Test for Weight A t0, Weight A t1

# 0 Differences	2
# Ties	2
Z-Value	-3.029
P-Value	.0025
Tied Z-Value	-3.029
Tied P-Value	.0025

Wilcoxon Rank Info for Weight A t0, Weight A t1

	Count	Sum Ranks	Mean Rank
# Ranks < 0	6	44.000	7.333
# Ranks > 0	18	256.000	14.222

Wilcoxon Signed Rank Test for Weight B t0, Weight B t1

# 0 Differences	1
# Ties	6
Z-Value	-2.814
P-Value	.0049
Tied Z-Value	-2.815
Tied P-Value	.0049

One case was omitted due to missing values.

Wilcoxon Rank Info for Weight B t0, Weight B t1

	Count	Sum Ranks	Mean Rank
# Ranks < 0	9	51.500	5.722
# Ranks > 0	15	248.500	16.567

One case was omitted due to missing values.

Wilcoxon Signed Rank Test for Area A t0, Area A t1

# 0 Differences	0
# Ties	0
Z-Value	-3.721
P-Value	.0002
Tied Z-Value	-3.721
Tied P-Value	.0002

Wilcoxon Rank Info for Area A t0, Area A t1

	Count	Sum Ranks	Mean Rank
# Ranks < 0	5	29.000	5.800
# Ranks > 0	21	322.000	15.333

Wilcoxon Signed Rank Test for Area B t0, Area B t1

# 0 Differences	0
# Ties	0
Z-Value	-4.211
P-Value	<.0001
Tied Z-Value	-4.211
Tied P-Value	<.0001

One case was omitted due to missing values.

Wilcoxon Rank Info for Area B t0, Area B t1

	Count	Sum Ranks	Mean Rank
# Ranks < 0	3	6.000	2.000
# Ranks > 0	22	319.000	14.500

One case was omitted due to missing values.

proDERM

Institut für Angewandte Dermatologische Forschung

Appendix E

Studien Synopsis

Studie:	99.110-11 / BANF 10524807
Versuchszeitraum:	02.11.99 bis 14.12.99
Titel:	Wirksamkeitsnachweis für Anti-Schuppenprodukte
Studienziel:	Quantifizierung des Einflusses zweier Anti-Schuppen Produkte auf Zahl und Größe von Kopfschuppen
Sponsor:	Clariant GmbH
Sponsor Contact/ Monitor:	Dr. A. Turowski
Studienleiter:	Priv.- Doz. Dr. K.-P. Wilhelm, Dermatologe
Studienort:	*proDERM* Institut für Angewandte Dermatologische Forschung, Industriestr. 1, 22869 Schenefeld/Hamburg
Test-Produkte:	Zn-Pyrrithion (ZPT) 0.3 % Octopirox 0.3 % Zusätzlich: Placebo in der Auswaschphase Lagerung bei Raumtemperatur (die genaue Produktbezeichnung ist dem Lieferschein der Testmaterialien zu entnehmen)
Test Areal:	Capilitium
Probanden:	50 Probanden, Alter über 18 Jahre, beiderlei Geschlechts, ohne Auffälligkeiten (z.B. akuter Psoriasis Schub) im Testbereich
Dauer der Studie:	6 Wochen pro Proband
Testbedingungen:	randomisiert Die Testdurchführung erfolgt in Anlehnung an die GCP-Richtlinien.
Applikationsmenge:	ad lib. pro Proband. Anwendungshäufigkeit wird dokumentiert

Bewertung: subjektive Beurteilung durch den Probanden
gravimetrische Bestimmung der Schuppenmenge
Bildanalyse der Schuppenmenge nach Zahl und Größe

Methoden

Vor Versuchsbeginn erfolgt eine zweiwöchige Auswaschphase, in der die Probanden die Haare mit einem Placeboprodukt waschen.
In der darauffolgenden vierwöchigen Anwendungsphase wendet jeder Proband eines der beiden Testprodukte an. Die Zuordnung erfolgt randomisiert.

Nach Anwendung des Placebo und nach Produktanwendung finden folgende Untersuchungen statt. 2 Tage vor jeder Untersuchung darf sich der Proband die Haare nicht mehr waschen:
1) Befragung zu Symptomen (Juckreiz, Brennnen) und Wirkung des Produktes
2) Auskämmen der vorhanden Schuppen aus dem Frontalbereich des Kopfes.
3) Gravimetrische Bestimmung der Schuppenmenge
4) Bildanalyse der Schuppen nach Zahl und Größe

Protokoll Synopsis akzeptiert

28.10.1999 Turowski
Datum, Dr. A. Turowski

27.10.1999 i.V. K. Wilhelm
Datum, Priv.-Doz. Dr. K.-P. Wilhelm (ARTICUS)

Clariant

Clinical Study to evaluate the Anti-dandruff Efficacy of Shampoos with Octopirox and Zn-Pyrithione at proDERM Institute

Hamburg, Germany, November 02 to December 14, 1999

Method:

Panelists:	51
Run-in-phase:	2 weeks with placebo shampoo
Experimental survey period:	4 weeks
Shampoo usage frequency:	under practical conditions
Active:	0,3 % Octopirox vs. 0,3 % Zinc Pyrithione

Quantification of the Efficacy:

1. Scalp scales measured by weight before and after treatment
2. Image analysis: number & size of scalp scales determined, classified into 11 categories, number of scalp scales per category counted
3. Subjective evaluation

Div. FUN
Dr. Peter Klug
octopirox studie.ppt, Feb. 2000

Clariant

Shampoo Composition:

	A	B
Genapol LRO *Sodium Laureth Sulfate*	46,40 %	46,40 %
Octopirox *Piroctone Olamine*	0,30 %	-
Zinkpyrithione *Zinc Pyrithione*	-	0,30 %
Belsil DMC 6032 *Dimethicone Copolyol Acetate*	0,50 %	0,50 %
Merquat 550 *Polyquaternium-7*	0,50 %	0,50 %
Genapol TSM *PEG-3 Distearate, Sodium Laureth Sulfate*	2,00 %	2,00 %
Genagen CAB *Cocamidopropyl Betaine*	6,70 %	6,70 %
Genapol L-3 *Laureth-3*	1,10 %	1,10 %
Sodium Chloride	2,00 %	2,00 %
Preservative	0,05 %	0,05 %
Water	ad 100	ad 100

Clariant

Results: 1. Gravimetric Determination (weight of scalp scales)

	weight before treatment	weight after treatment
Octopirox	5,52	2,33
ZPT	9,57*	2,11

* high baseline for ZPT because of 3 panelists with extreme dandruff

= Comparable gravimetric results for Octopirox vs. ZPT

Clariant

Results: 1. Gravimetric Determination (weight of scalp scales)
2. Image Analysis (area of scalp scales)

	weight before treatment	weight after treatment	area before treatment	area after treatment
Octopirox	5,52	2,33	307	44
ZPT	9,57*	2,11	278	29

* high baseline for ZPT because of 3 panelists with extreme dandruff

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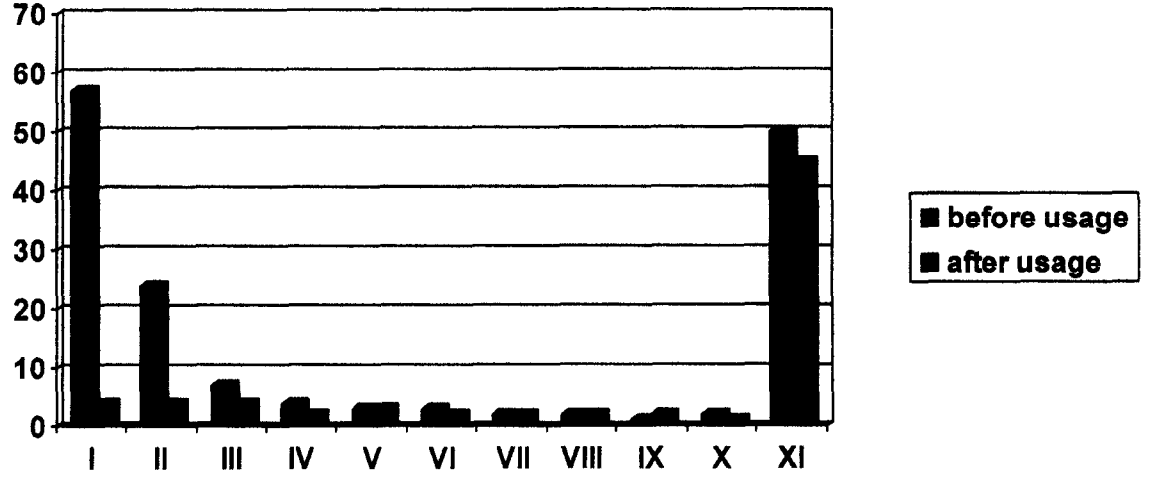
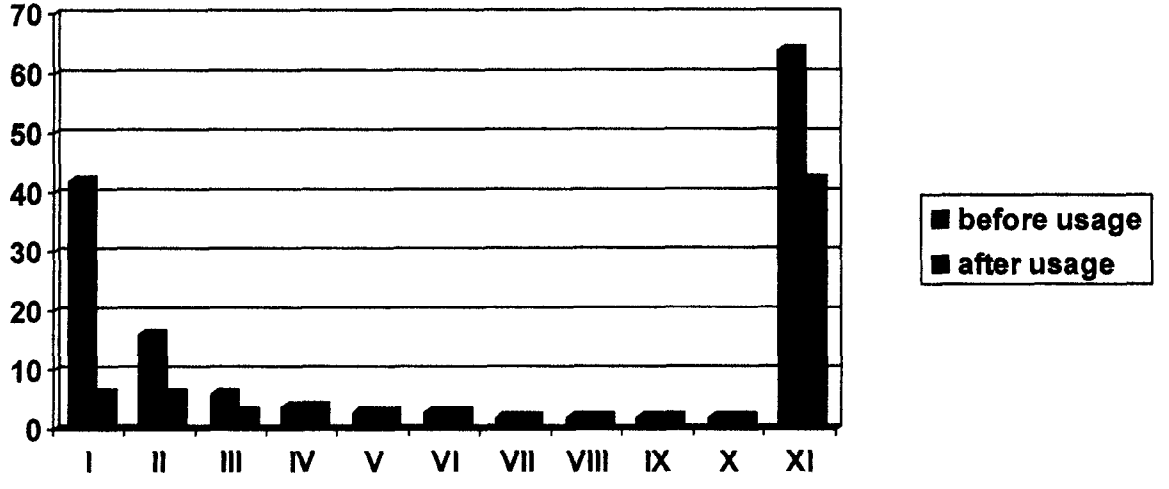
Results: 2. Image analysis: Scalp scales per size category

Octopirox



ZPT



Clariant

3. Subjective Evaluation:

Improvement of scalp scale related symptoms was noted for both products

Summary

- reduction in small scalp scales decreased by both products
- number of large scalp scales remained nearly constant
- comparable performance of both products within the error limits
- even at a concentration of 0,3 % Octopirox a clear differentiation to the baseline was observed

R&D Personal Care

Clariant GmbH
Division Functional Chemicals
D-65926 Frankfurt am Main

Clariant

ANTIDANDRUFF SHAMPOO

Si222/

Recipe

	1	2
GENAPOL LRO *Sodium Laureth Sulfate*	46.40 %	46.40 %
OCTOPIROX *Piroctone Olamine*	0.30 %	-
ZINKPYRITHONE *Zinc Pyrithione*	-	0.62 %
BELSIL DMC 6032 *Dimethicone Copolyol Acetate*	0.50 %	0.50 %
MERQUAT 550 *Polyquaternium-7*	0.50 %	0.50 %
GENAPOL TSM *PEG-3 Distearate, Sodium Laureth Sulfate*	2.00 %	2.00 %
GENAGEN CAB *Cocamidopropyl Betaine*	6.70 %	6.70 %
GENAPOL L-3 *Laureth-3*	1.10 %	2.50 %
SODIUM CHLORIDE	2.00 %	2.00 %
EUXYL K 400	0.05 %	0.05 %
WATER	ad 100	ad 100

This information is based on our present state of knowledge and is intended to provide general notes on our products and their uses. It should not therefore be construed as guaranteeing specific properties of the product described or their suitability for a particular application. Any existing industrial property rights must be observed. The quality of our products is guaranteed under our General Conditions of Sale.

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R&D Personal Care

Clariant GmbH
Division Functional Chemicals
D-65926 Frankfurt am Main

Clariant

ANTIDANDRUFF SHAMPOO

Si222/

Recipe

	1	2
GENAPOL LRO *Sodium Laureth Sulfate*	46.40 %	46.40 %
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ZINKPYRITHONE *Zinc Pyrithione*	-	0.62 %
BELSIL DMC 6032 *Dimethicone Copolyol Acetate*	0.50 %	0.50 %
MERQUAT 550 *Polyquaternium-7*	0.50 %	0.50 %
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SODIUM CHLORIDE	2.00 %	2.00 %
EUXYL K 400	0.05 %	0.05 %
WATER	ad 100	ad 100

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