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0.75% PIROCTONE OLAMINE SHAMPOO vs.
1.0% DTPD/MgSO₄ SHAMPOO
COMPARATIVE TRIAL OF ANTIDANDRUFF EFFICACY USING
THE HALF-HEAD TECHNIQUE

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1.0% DTPD/MgSO4 SHAMPOO
COMPARATIVE TRIAL OF ANTIDANDRUFF EFFICACY USING
THE HALF-HEAD TECHNIQUE

LSR Report No. : 84/HAG093/336

We, the undersigned, hereby declare that the report following constitutes a true and faithful account of the procedures adopted, and the results obtained, in the performance of this study.

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(Study Director,
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S U M M A R Y

1. Thirty-four subjects who completed the trial received 0.75% Piroctone Olamine shampoo and 1.0% DTPD/MgSO₄ shampoo, one product on each side of the head, once weekly for six weeks. This was preceded by two weeks ad lib home use of an inactive shampoo. Application of the test shampoo and hair washing were performed by professional hairdressers, supervised at all times by a member of Life Science Research staff.

2. Dandruff was assessed on a 0 - 80 scale, at screening (Day -14), two days before the first treatment and on Days 14, 28 and 42.

The mean dandruff score after two weeks ad lib usage of the inactive shampoo was 19.5 for the sides of the head which were to receive 0.75% Piroctone Olamine shampoo and 19.3 for the sides of the head which were to receive 1.0% DTPD/MgSO₄ shampoo. After six treatments with 0.75% Piroctone Olamine shampoo the mean dandruff score was 11.3 (42.0% reduction) while for 1.0% DTPD/MgSO₄ shampoo the mean score was 14.7 (23.8% reduction).

The differences between the mean dandruff scores were statistically significant only after six treatments ($p < 0.02$). The significance of this difference was also $p < 0.02$ for the 'area only' scores.

3. Subjects own assessment of dandruff showed a general decrease associated with both shampoos from Day -2 to Day 28 (2.1 to 1.6 units), and after six treatments the mean scores had both increased slightly to 1.7.
4. For hair dryness/greasiness, there were no significant differences observed between the products either by the examiners or the subjects themselves.
5. An overall reduction was recorded in the subjects assessment of scalp itching. 0.75% Piroctone Olamine shampoo was associated with a slightly greater reduction (47.1%) than 1.0% DTPD/MgSO₄ shampoo (41.2%) after six weeks of treatment.

METHODS

1. Selection of subjects

1.1 Forty-five males and females were examined to assess the amount and severity of dandruff present. Subjects were asked not to shampoo their hair for six days prior to the screening examinations.

1.2 Excluded from the trial were:

Females admitting to being pregnant or nursing mothers.

Volunteers who had seborrheic dermatitis or psoriasis with visible inflammation of the scalp.

Volunteers who were undergoing medical treatment for a scalp condition.

Volunteers who were under 16 years of age on the screening day.

Volunteers who intended to tint or perm their hair during the trial.

1.3 Signed informed consent witnessed by a member of Life Science Research staff, was obtained from each subject admitted to the study, signed consent was also obtained from a parent or guardian for those subjects under 18 years of age at the start of the trial.

1.4 Thirty-five subjects were selected on the basis of their dandruff score, and were issued with the inactive shampoo to use at home ad lib for two weeks, except for the six days before the next assessment. As they were unable to attend the screening assessment, an additional four volunteers were sent the inactive shampoo and instructions.

1.5 Two days before the first treatment, 35 subjects were assessed and were all selected on the basis of their dandruff scores to proceed with the treatment period.

2. Allocation to treatment groups

2.1 For two weeks immediately preceding treatment, except for the final six days, subjects used the inactive shampoo at home ad lib according to instructions provided. For the remainder of the study, subjects were allocated to two treatment groups so that seventeen subjects received 0.75% Piroctone Olamine shampoo on the left side of the head throughout the trial, and eighteen subjects received this shampoo on the right side of the head; 1.0% DTPD/MgSO₄ shampoo was applied to each head on the alternate side.

2.2 Allocation was made in such a way that the mean half-head scores (area x severity) for the left and right sides of the head were balanced as far as possible.

3. Product presentation and description

3.1 Product presentation

The inactive shampoo was presented in 50 ml white plastic bottles with white screw-top caps. Each bottle bore labels as follows:

Shampoo No. 884-i

Wet the hair and apply shampoo.
Lather and rinse. Repeat the application, then rinse again.
Caution: Not to be taken internally.
Keep out of children's reach.
Avoid getting shampoo in eyes.
If this happens, rinse eyes with water.

Distributed by: Life Science
Research Tel. (0245) 252878

Shampoo
No. 884-i

0.75% Piroctone Olamine shampoo was presented in 200 ml pale yellow plastic bottles with orange plastic flip-top caps. Each bottle bore the following label:

Shampoo
No. 884 OH

1.0% DTPD/MgSO₄ shampoo was presented in 200 ml pale yellow plastic bottles with pink plastic flip-top caps. Each bottle bore the following label:

Shampoo
No. 884 MO

3.2 Product description

The inactive shampoo (884-i) is based on an anionic surfactant, which was also used as the base for both active shampoos (884 OH and 884 MO). The preservative agents present in 884-i were omitted from 884 OH and 884 MO shampoos. The active ingredient in shampoo 884 OH is 0.75% (w/w) Piroctone Olamine (1-hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2(1H)-Pyridone compound with 2-aminoethanol (1:1)) while in shampoo 884 MO it is 1.0% DTPD/MgSO₄ (1.00% (w/w) Bis-pyrithione magnesium sulphate (2,2'-dithiobis-pyridine 1,1'-dioxide compound with magnesium sulphate (1:1))).

The pH of the active shampoos has been adjusted from 6.5 to 7.0.

4. Treatment

4.1 Treatment was once weekly on Days 0, 7, 14, 21, 28 and 35 though a more frequent washing regime would have been preferred by some subjects.

4.2 Hair washing

Application of the shampoos to the scalp and washing of the hair was performed by professional hairdressers, supervised at all times by Life Science Research staff. Each half-head treatment consisted of two separate applications of either 5 or 10 ml of shampoo, the total amount varying between subjects according to the length and thickness of the hair. Equal amounts were applied to both sides of the head throughout except for subject 11 who received a total of 10 ml on Day 0 and 20 ml thereafter. The hair was parted at the midline and secured on one side with clips. The subject's head was then positioned so that the head was over a wash basin and tilted towards the side to be washed. Shampoo was then applied directly to the scalp at several places by the hairdresser and gently distributed up to the parting with the tips of the fingers. In view of the angle of the head, there was no difficulty in keeping the shampoo within the required area. Careful rinsing of the area with a warm water spray was followed by a further application of shampoo, followed by rinsing, as described above. Surplus water was taken up by gentle mopping with a towel. The procedure was then repeated using the alternative product on the other side of the head, surplus water being taken up with a second towel. The hair was then dried and styled by a professional hairdresser according to the individual subjects' requirements, avoiding the use of setting lotion and hair lacquer.

5. Observations

Observations took place at a dandruff assessment centre, and were recorded while subjects were sitting under a 40-watt white fluorescent strip light 122 cm (4 ft) in length, positioned 183 cm (6 ft) above floor level. Observations were made at screening, two days before the first treatment, and on Days 14, 28 and 42. On Days 14 and 28, observations were made before subjects attended the salon for treatment.

5.1 Examiner's assessment of dandruff

The four quadrants of the scalp were separately assessed for dandruff in terms of the area of the scalp affected and severity. The hair was parted and secured with clips; the examiner then made successive partings in the quadrant concerned. The amount and type of dandruff on the scalp was assessed by observation, and by drawing the tip of the comb handle along the partings to ascertain whether the scales were loosely attached or adhering to the scalp.

Dandruff was scored according to the following criteria:

Area of quadrant affected

Less than 10%	0
10% or more but less than 30%	1
30% or more but less than 50%	2
50% or more but less than 70%	3
70% or more	4

Severity

Small flakes resembling a coarse greyish white powder (Grade A)	1
Intermediate (Grade AB)	2
Large flakes very loosely attached to the scalp and giving an irregular whitish surface (Grade B)	3
Intermediate (Grade BC)	4
Flakes apparently congealed together into yellowish plates adhering to the scalp, sometimes with evidence of exudate and erythema (Grade C)	5
Small flakes as "A" partially adhering to scalp as "C" (Grade AC)	3

For each quadrant, the score for area was multiplied by the score for severity. The scores for two quadrants on one side were then added together. The maximum possible score for one side was therefore $(4 \times 5) \times 2 = 40$. The examiners were not aware of the particular treatments allocated to the individual subjects.

5.2 Subject's assessment of dandruff

Subjects were asked to assess their dandruff on each side of the head according to the following scale:

Which best describes your dandruff today?

	<u>Left side</u>	<u>Right side</u>
None	0	0
Slight	1	1
Moderate	2	2
Severe	3	3
Very severe	4	4

5.3 Assessment of hair dryness/greasiness

The examiner assessed each subject's hair dryness/greasiness by observing and feeling with the fingers, several sections of the hair at or near the roots on both sides of the head. Assessments were made according to the following scale:

<u>Hair condition</u>	<u>Left side</u>	<u>Right side</u>
Very dry	0	0
Dry	1	1
Normal	2	2
Greasy	3	3
Very greasy	4	4

At each session, subjects were asked to assess the dryness/greasiness of their hair according to the above scale.

5.4 Subject's assessment of scalp itching

Subjects were asked to assess their scalp itching on each side of the head according to the following scale:

Which best describes your scalp itching today?

	<u>Left side</u>	<u>Right side</u>
None	0	0
Mild	1	1
Moderate	2	2
Severe	3	3
Very severe	4	4

6. Sample of water

A one litre sample of tap water was taken from the salon on Day 28 of the trial, and is held at Life Science Research.

7. Statistical analysis

The statistical analysis was based on the scores of those subjects who finished the trial. The significance of changes in dandruff scores (area x severity and area only) between treatments was assessed by the Students 't' test. The difference between the overall responses to each treatment in terms of subjects' own dandruff assessments was analysed by the Sign test¹.

8. Storage of data

All raw data relating to this study are stored in the Archives of Life Science Research for a minimum of five years.

Reference

1. Walsh J.E. (1946) On the power function of the Sign test for slippage of means. *Annals of Mathematical Statistics* 17.

R E S U L T S

1. Locations and dates of trial

Assessments of dandruff took place at Chelmer Village Hall, Chelmer Village, Springfield, Essex, U.K. on 13 and 25 April, 11 and 25 May and 8 June 1984. Salon treatments took place at Bodmin Hair Shop, Bodmin Road, Springfield, Essex, U.K. on 27 April, 4, 11, 18 and 25 May and 1 June 1984.

All dandruff assessments and salon treatments took place as indicated above, apart from the subjects listed below:

Subject number	Assessment/ treatment missed		Assessment/ treatment performed		Place	Remarks
	Day	Date	Day	Date		
29	0	27.4.84	-1	26.4.84	Salon facility CTC International Chelmsford, Essex	Supervised by a member of CTC International staff
35	0	27.4.84	1	28.4.84	As above	As above
10	7	4.5.84	6	3.5.84	As above	As above
7	42	8.6.84	43	9.6.84	Ingatstone, Essex	Grading performed under standard lighting by a member of CTC staff
13	42	8.6.84	45	11.6.84	Test facility CTC International Chelmsford, Essex	As above

2. Subjects completing the trial

Of the thirty-five subjects admitted to the trial, only one (Number 35) dropped out after one treatment for reasons unconnected with the trial.

3. Final group sizes

Sixteen subjects (12 women and 4 men) were in the group which received 0.75% Piroctone Olamine shampoo on the left side of the head and 1.0% DTPD/MgSO₄ shampoo on the right. Eighteen subjects (15 women and 3 men) were in the group which received these shampoos on the alternate sides.

4. Dandruff - examiners assessments

4.1 Scores for area x severity (Figure 1, Table 1, Appendix 1)

4.1.1 Antidandruff efficacy of 0.75% Piroctone Olamine shampoo

For the 34 finishers, the mean examiners score for dandruff on the sides of the head to be treated with 0.75% Piroctone Olamine shampoo was 19.5 after two weeks usage of the inactive shampoo.

The mean scores after two, four and six treatments were 14.7, 12.3 and 11.3 representing reductions of 24.6%, 36.9% and 42.0% respectively.

4.1.2 Antidandruff efficacy of 1.0% DTPD/MgSO4 shampoo

For the 34 finishers the mean dandruff scores for the side of the head to be treated with 1.0% DTPD/MgSO4 shampoo was 19.3 units after two weeks ad lib usage of the inactive shampoo.

The mean scores after two, four and six treatments of 1.0% DTPD/MgSO4 shampoo were 15.7, 13.9 and 14.7 units respectively. These scores represent reductions of 18.7%, 28.0% and 23.8% respectively.

4.1.3 Comparative antidandruff efficacy of 0.75% Piroctone Olamine Shampoo and 1.0% DTPD/MgSO4 shampoo

There was no significant difference between the shampoos after two and four treatments but, after six treatments, 0.75% Piroctone Olamine shampoo was significantly better ($p < 0.02$) than 1.0% DTPD/MgSO4 shampoo.

4.2 Scores for area only (Figure 1, Table 2, Appendix 2)

0.75% Piroctone Olamine shampoo produced a decrease in mean value from 5.4 at Day -2 to 3.4 after six treatments representing a reduction of 37.0%.

1.0% DTPD/MgSO4 shampoo also produced a decrease in the mean score from 5.4 at Day -2 to 3.7 after four treatments. A slight increase to 4.2 was observed after six treatments.

The difference between products, for area scores only, was not statistically significant until Day 42 ($p < 0.02$) the same level of significance as was reached for (area x severity) scores. The overall trends for both 'area x severity' and 'area only' scores are also very similar (Figure 1).

5. Dandruff - subjects assessment
(Appendix 3)

Subjects assessed their dandruff on a 0 - 4 scale. After using the inactive shampoo at home ad lib for two weeks, the mean score was 2.1 units for both sides of the head.

The mean scores obtained for both shampoos were the same throughout.

After two and four treatments there was a slight reduction in the mean score from 1.9 to 1.6, and after six treatments the mean score increased to 1.7 units.

6. Comparison of examiners' and subjects' assessments of dryness/greasiness of the hair
(Appendices 4 and 5)

Both examiners' and subjects' assessments indicated an increase in mean scores for both test shampoos from the Baseline at Day -2 to Day 28. On Day 42, after six treatments, the examiners score for the sides of the head treated with 0.75% Piroctone Olamine shampoo did not change (2.7) while the score for the sides of the head treated with 1.0% DTPD/MgSO₄ shampoo had reduced slightly (from 2.7 to 2.6). The subjects assessment showed a decrease in mean score for both products from Day 28 to Day 42 (from 2.4 to 2.3).

The similarity of the scores for the products indicates that there is no difference in the amount of resoiling between the products.

7. Scalp itching - subjects assessment
(Appendix 6)

Subjects assessed their scalp itching on a 0 - 4 scale. At Day -2 the scores for sides of the head to be treated with each shampoo were 1.7. After two and four treatments there was a reduction in the mean scores to 1.2 and 1.0 units respectively. After six treatments there was a slightly greater reduction in the mean score for the sides of the head treated with 0.75% Piroctone Olamine shampoo (to 0.9 units) than for the sides treated with 1.0% DTPD/MgSO₄ shampoo (to 1.0 units).

FIGURE 1

Mean dandruff scores for all attenders before and after once-weekly treatments with 0.75% Piroctone Olamine shampoo (OH) and 1.0% DTPD/MgSO4 shampoo (MO)

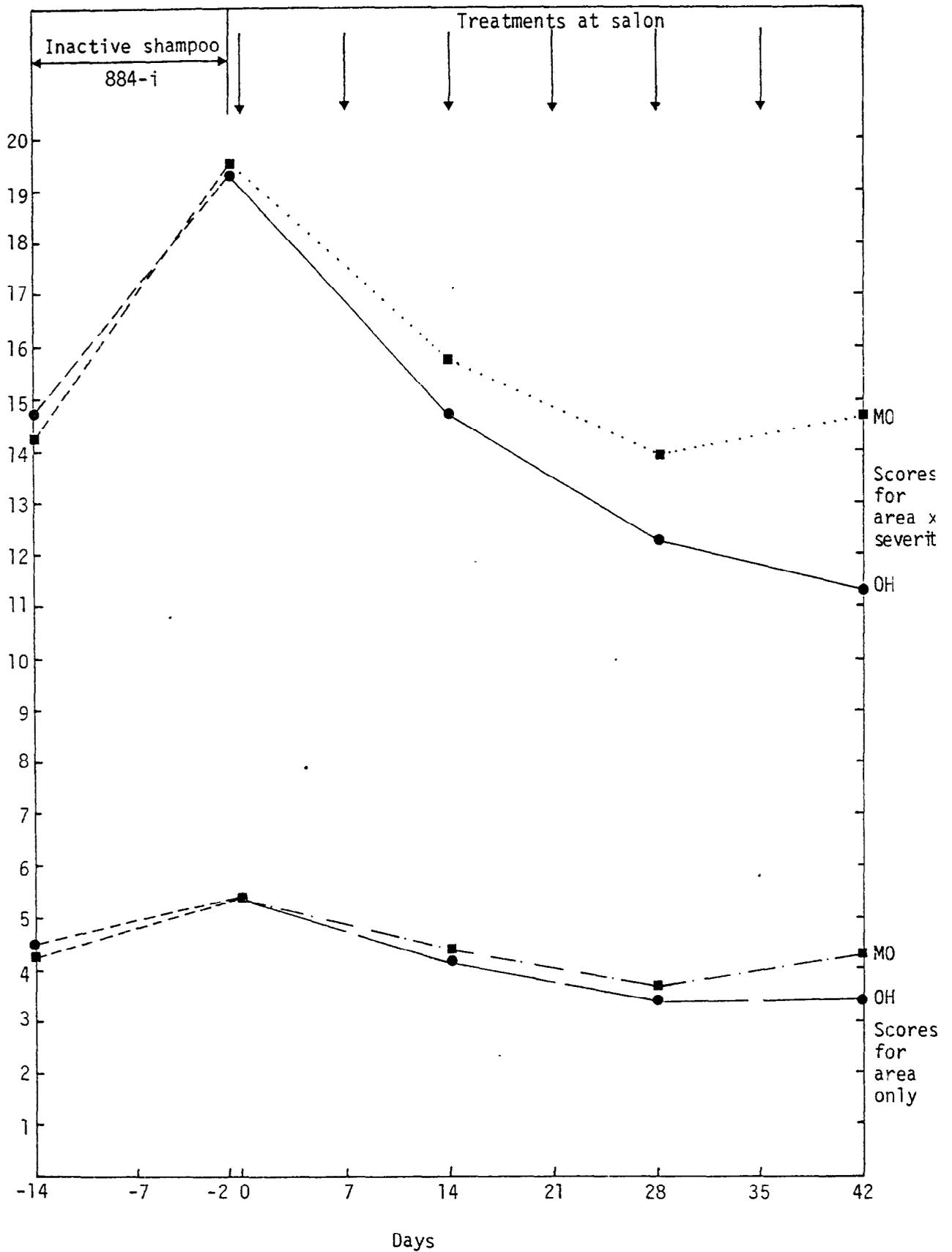


TABLE 1

Antidandruff efficacy (area x severity) of 0.75% Piroctone Olamine shampoo and 1.0% DTPD/MgSO4 shampoo

Comparison of mean reductions in half-head dandruff scores after 2, 4 and 6 treatments

	At screening (Day -14)	Baseline (Day -2)	Days since start of treatment		
			14	28	42
0.75% Piroctone Olamine shampoo (n)	15.1 (32)	19.5 (34)	14.7 (34)	12.3 (34)	11.3 (34)
1.0% DTPD/MgSO4 shampoo (n)	14.3 (32)	19.3 (34)	15.7 (34)	13.9 (34)	14.7 (34)
0.75% Piroctone Olamine shampoo mean reduction from baseline score of all finishers (% reduction)			4.8 (24.6)	7.2 (36.9)	8.2 (42.0)
1.0% DTPD/MgSO4 shampoo mean reduction from baseline score of all finishers (% reduction)			3.6 (18.7)	5.4 (28.0)	4.6 (23.8)
Difference between products			1.2	1.8	3.6
p			> 0.05	> 0.05	< 0.02

n = Number of subjects

TABLE 2

Antidandruff efficacy (area scores only) of 0.75% Piroctone Olamine shampoo and 1.0% DTPD/MgSO4 shampoo

Comparison of mean reductions in half-head dandruff scores after 2, 4 and 6 treatments

	At screening (Day -14)	Baseline (Day -2)	Days since start of treatment		
			14	28	42
0.75% Piroctone Olamine shampoo (n)	4.5 (32)	5.4 (34)	4.2 (34)	3.5 (34)	3.4 (34)
1.0% DTPD/MgSO4 shampoo (n)	4.3 (32)	5.4 (34)	4.3 (34)	3.7 (34)	4.2 (34)
0.75% Piroctone Olamine shampoo mean reduction from baseline score of all finishers (% reduction)			1.2 (22.2)	1.9 (35.2)	2.0 (37.0)
1.0% DTPD/MgSO4 shampoo mean reduction from baseline score of all finishers (% reduction)			1.1 (20.4)	1.7 (31.5)	1.2 (22.2)
Difference between products			0.1	0.2	0.8
p			> 0.05	> 0.05	< 0.02

n = Number of subjects

APPENDIX 1

Half-head scores left (L) and right (R) for dandruff (area x severity) before and after once-weekly treatments with 0.75% Piroctone Olamine shampoo (OH) and 1.0% DTPD/MqS04 shampoo (MO)

Subject number	Sex	At screening (Day -14)		After 2 weeks inactive shampoo baseline (Day -2)		Days since start of treatment					
		L	R	L	R	14		28		42	
						OH L	MO R	OH L	MO R	OH L	MO R
1	F	8	6	6	6	18	32	15	40	10	18
2	F	30	30	25	25	25	15	23	19	22	12
3	F	16	12	24	20	4	4	12	4	8	8
4	F	24	24	32	32	28	32	28	20	24	28
7	M	15	10	5	18	12	11	6	8	18	18
8	M	5	3	24	28	16	16	12	8	12	16
9	F	12	11	24	24	6	3	14	7	20	9
10	F	8	9	10	10	8	0	6	2	0	3
11	F	21	18	16	15	28	15	21	15	21	18
20	F	15	9	21	17	21	14	5	3	0	0
24	F	21	18	24	28	21	32	20	28	21	28
25	M	7	4	15	12	11	18	9	11	2	14
26	F	18	19	28	25	19	25	16	20	21	28
27	M	4	6	21	10	7	0	6	4	4	1
31	F	9	6	17	14	0	3	10	3	8	9
33	F	21	21	17	20	21	21	21	24	15	24
35	M	8	3	16	24	-	-	-	-	-	-
		R	L	R	L	R	L	R	L	R	L
5	F	21	13	18	14	16	16	12	15	20	18
6	F	6	9	12	14	3	11	4	3	3	14
12	F	12	18	21	18	3	14	3	12	9	16
13	F	40	40	40	40	40	40	40	40	27	27
14	M	18	18	24	28	16	18	9	24	6	25
15	M	21	24	40	40	24	28	15	22	7	28
16	F	9	9	24	24	11	10	16	20	10	16
17	F	9	7	17	18	2	9	9	12	18	9
18	F	25	12	15	18	15	18	3	6	3	9
19	F	8	20	9	9	6	9	5	11	3	14
21	F	*	*	18	8	15	18	18	15	18	12
22	F	6	9	15	18	12	20	7	12	3	12
23	F	21	21	21	21	16	18	15	10	15	21
28	F	11	8	12	18	9	1	6	6	7	4
29	F	*	*	23	16	23	24	12	24	10	28
30	M	13	18	17	14	20	12	12	16	10	7
32	F	12	6	12	15	8	8	3	0	6	6
34	F	16	20	15	20	5	20	4	8	4	0
Mean score		14.3	14.1	19.4	19.5	14.7	15.7	12.3	13.9	11.3	14.7
(n)		(33)	(33)	(35)	(35)	(34)	(34)	(34)	(34)	(34)	(34)
Mean score all finishers		15.1	14.3	19.5	19.3	14.7	15.7	12.3	13.9	11.3	14.7
(n)		(32)	(32)	(34)	(34)	(34)	(34)	(34)	(34)	(34)	(34)

* Subjects unable to attend screening, inactive shampoo posted on Day -14.

APPENDIX 2

Half-head scores left (L) and right (R) for dandruff (area scores only) before and after once-weekly treatments with 0.75% Piroctone Olamine shampoo (OH) and 1.0% OTPD/MgSO4 shampoo (MO).

Subject number	Sex	At screening (Day -14)		After 2 weeks inactive shampoo baseline (Day -2)		Days since start of treatment					
		L	R	L	R	14		28		42	
						OH L	MO R	OH L	MO R	OH L	MO R
1	F	3	2	2	2	6	7	4	8	3	6
2	F	6	6	5	5	5	3	5	4	5	3
3	F	4	3	6	5	1	1	3	1	2	2
4	F	8	6	8	8	8	8	7	6	6	8
7	M	5	4	3	6	6	5	3	2	6	5
8	M	2	1	6	7	4	4	3	2	4	4
9	F	3	3	6	6	2	1	4	2	5	3
10	F	2	3	3	3	2	0	2	2	0	1
11	F	7	6	8	7	8	5	7	5	7	6
20	F	5	3	6	5	6	4	3	1	0	0
24	F	7	6	7	7	6	8	5	7	6	7
25	M	3	4	5	4	5	6	3	3	2	4
26	F	6	5	8	7	5	7	5	5	6	7
27	M	1	2	6	5	3	0	2	2	1	1
31	F	3	2	5	4	0	1	3	1	2	3
33	F	7	7	5	5	7	7	7	8	5	7
35	M	4	4	5	6	-	-	-	-	-	-
5	F	6	5	5	4	4	4	3	5	5	6
6	F	2	3	4	4	1	3	1	1	1	4
12	F	4	5	6	5	1	4	1	3	3	4
13	F	8	8	8	8	8	8	8	8	7	7
14	M	6	5	6	7	4	5	3	6	2	7
15	M	7	8	8	8	8	8	5	5	2	7
16	F	3	3	6	6	3	3	4	5	3	4
17	F	3	2	5	6	4	3	3	4	6	3
18	F	7	4	5	6	5	6	1	2	1	3
19	F	3	5	3	3	2	3	2	3	1	4
21	F	*	*	5	4	5	6	6	5	6	4
22	F	2	3	5	6	4	5	2	4	1	4
23	F	5	7	7	7	4	5	4	3	5	6
28	F	5	4	4	6	3	1	2	2	3	2
29	F	*	*	5	4	5	6	3	6	3	7
30	M	4	6	5	4	5	4	3	4	3	3
32	F	3	2	4	5	2	2	1	0	2	2
34	F	4	5	3	4	1	4	1	2	1	0
Mean score		4.5	4.3	5.4	5.4	4.2	4.3	3.5	3.7	3.4	4.2
(n)		(33)	(33)	(35)	(35)	(34)	(34)	(34)	(34)	(34)	(34)
Mean score all finishers		4.5	4.3	5.4	5.4	4.2	4.3	3.5	3.7	3.4	4.2
(n)		(32)	(32)	(34)	(34)	(34)	(34)	(34)	(34)	(34)	(34)

* Subjects unable to attend screening, inactive shampoo posted on Day -14.

APPENDIX 3

Subjects self-assessment of dandruff on left (L) and right (R) sides of the head before and after once-weekly treatments with 0.75% Piroctone Olamine shampoo (OH) and 1.0% DTPD/MgSO4 shampoo (MO)

Subject number	Sex	At screening (Day -14)		After 2 weeks inactive shampoo baseline (Day -2)		Days since start of treatment					
		L	R	L	R	14		28		42	
						OH L	MO R	OH L	MO R	OH L	MO R
1	F	2	2	2	2	2	2	1	1	1	1
2	F	2	2	2	2	2	2	1	1	1	1
3	F	2	2	2	2	2	2	2	2	2	2
4	F	3	3	2	2	3	3	3	2	2	1
7	M	4	4	3	3	2	2	2	2	3	3
8	M	2	1	2	2	2	2	3	3	3	3
9	F	2	2	2	2	2	1	1	1	2	1
10	F	2	2	2	2	1	2	1	2	1	2
11	F	1	1	3	3	3	3	2	2	1	1
20	F	2	2	3	3	2	2	1	2	1	1
24	F	1	1	2	2	2	2	2	2	2	2
25	M	1	1	3	3	3	3	2	2	2	2
26	F	1	1	2	2	1	1	1	1	2	2
27	M	1	1	2	2	1	1	1	1	1	1
31	F	2	2	2	2	2	1	2	2	2	2
33	F	1	1	2	2	1	1	2	2	1	1
35	M	3	3	3	3	-	-	-	-	-	-
<hr/>											
		R	L	R	L	R	L	R	L	R	L
5	F	1	1	1	1	1	2	2	1	2	3
6	F	3	3	2	2	2	2	2	2	1	1
12	F	1	1	1	1	1	1	1	1	1	1
13	F	3	3	3	3	2	3	2	3	3	2
14	M	2	2	1	1	1	1	2	2	2	2
15	M	3	3	3	3	3	3	2	2	2	2
16	F	2	2	2	2	2	2	2	2	2	2
17	F	1	1	1	1	1	1	1	1	1	1
18	F	2	2	2	2	2	2	1	1	1	1
19	F	2	2	1	1	2	2	1	1	3	3
21	F	*	*	2	2	2	2	2	1	2	2
22	F	1	1	1	1	2	2	0	0	1	1
23	F	1	1	2	2	2	2	1	1	2	2
28	F	2	2	3	3	1	1	2	2	2	2
29	F	*	*	3	3	3	3	2	2	2	2
30	M	2	2	2	2	2	2	2	2	2	2
32	F	1	1	3	3	2	2	2	2	1	1
34	F	2	2	2	4	3	3	1	2	2	2
<hr/>											
Mean score		1.8	1.8	2.1	2.1	1.9	1.9	1.6	1.6	1.7	1.7
(n)		(33)	(33)	(35)	(35)	(34)	(34)	(34)	(34)	(34)	(34)
<hr/>											
Mean score all finishers		1.8	1.8	2.1	2.1	1.9	1.9	1.6	1.6	1.7	1.7
(n)		(32)	(32)	(34)	(34)	(34)	(34)	(34)	(34)	(34)	(34)

* Subjects unable to attend screening, inactive shampoo posted on Day -14.

APPENDIX 4

Examiners scores left (L) and right (R) for hair dryness/greasiness before and after once-weekly treatments with 0.75% Piroctone Olamine shampoo (OH) and 1.0% DTPD/McSO4 shampoo (MO)

Subject number	Sex	At screening (Day -14)		After 2 weeks inactive shampoo baseline (Day -2)		Days since start of treatment					
		L	R	L	R	14		28		42	
						OH L	MO R	OH L	MO R	OH L	MO R
1	F	1	1	1	1	1	1	2	1	2	2
2	F	0	0	1	1	1	1	1	1	1	1
3	F	2	2	4	4	4	4	4	4	3	3
4	F	2	2	2	2	3	3	3	3	3	3
7	M	2	2	2	2	2	2	3	3	2	2
8	M	2	2	2	2	2	2	3	3	3	3
9	F	3	3	3	3	4	4	4	4	4	3
10	F	3	3	3	3	3	3	4	4	4	4
11	F	4	4	3	3	4	4	4	4	4	4
20	F	1	1	1	1	1	1	2	2	2	2
24	F	0	0	1	1	1	1	2	2	2	2
25	M	4	4	4	4	3	3	4	4	4	4
26	F	2	2	2	2	2	2	2	2	2	2
27	M	3	3	2	1	3	3	3	3	3	3
31	F	3	3	3	3	4	4	4	4	4	3
33	F	3	3	2	2	1	1	2	2	2	2
35	M	3	3	2	2	-	-	-	-	-	-
5	F					R	L	R	L	R	L
6	F	3	3	2	2	2	2	3	3	3	3
12	F	2	2	1	1	1	1	1	1	1	1
13	F	2	2	2	2	2	2	2	2	1	1
14	M	3	3	2	2	2	2	3	3	3	3
15	M	1	1	2	2	2	2	3	3	3	4
16	F	2	2	2	2	2	2	3	3	3	3
17	F	3	3	2	2	3	3	3	3	3	3
18	F	2	2	3	3	3	3	3	3	3	3
19	F	2	3	3	3	3	3	2	2	2	2
21	F	*	*	3	3	3	3	3	3	3	3
22	F	2	2	2	2	3	3	3	3	2	2
23	F	2	2	2	2	2	2	3	3	3	3
28	F	4	4	4	4	4	4	4	4	4	4
29	F	*	*	0	0	0	0	0	1	1	1
30	M	1	1	1	1	1	1	1	1	3	3
32	F	4	4	4	4	4	4	4	4	4	4
34	F	2	2	2	2	1	1	1	1	3	2
Mean score		2.2	2.3	2.2	2.1	2.3	2.3	2.7	2.7	2.7	2.6
(n)		(33)	(33)	(35)	(35)	(34)	(34)	(34)	(34)	(34)	(34)
Mean score all finishers		2.2	2.3	2.2	2.1	2.3	2.3	2.7	2.7	2.7	2.6
(n)		(32)	(32)	(34)	(34)	(34)	(34)	(34)	(34)	(34)	(34)

* Subjects unable to attend screening, inactive shampoo posted on Day -14.

APPENDIX 6

Subjects self-assessment of scalp itching on left (L) and right (R) sides of the head before and after once-weekly treatments with 0.75% Piroctone Olamine shampoo (OH) and 1.0% DTPG/MgSO4 shampoo (MO)

Subject number	Sex	At screening (Day -14)		After 2 weeks inactive shampoo baseline (Day -2)		Days since start of treatment					
		L	R	L	R	14		28		42	
						OH L	MO R	OH L	MO R	OH L	MO R
1	F	1	1	2	2	2	2	1	1	0	0
2	F	2	2	2	2	2	2	0	0	0	0
3	F	0	0	0	0	0	0	1	1	1	1
4	F	2	2	2	2	2	2	2	1	0	0
7	M	0	0	3	3	0	0	0	0	1	1
8	M	1	1	3	3	1	1	1	1	1	1
9	F	1	1	3	3	3	2	1	2	2	0
10	F	1	1	2	2	1	2	1	1	0	0
11	F	1	1	2	2	2	2	1	1	1	1
20	F	2	2	3	3	1	1	1	1	0	0
24	F	1	1	1	1	1	1	1	1	2	2
25	M	1	1	1	1	2	2	2	2	1	1
26	F	0	0	1	1	1	1	0	0	1	1
27	M	0	0	2	2	1	1	1	0	1	3
31	F	1	1	0	0	0	0	0	1	0	1
33	F	1	1	2	2	1	1	2	2	1	1
35	M	2	2	2	2	-	-	-	-	-	-
		R	L	R	L	R	L	R	L	R	L
5	F	1	1	1	1	2	2	1	2	2	3
6	F	1	1	1	1	1	1	0	0	0	0
12	F	1	1	1	1	0	0	1	1	0	0
13	F	0	0	1	1	0	0	1	1	0	0
14	M	0	0	2	2	0	0	1	1	1	1
15	M	0	1	1	1	2	2	2	1	2	2
15	F	1	1	0	0	0	0	1	1	0	0
17	F	3	3	2	2	1	1	1	1	0	1
18	F	0	0	0	0	1	1	0	0	0	0
19	F	2	2	2	2	1	1	1	0	3	2
21	F	*	*	1	1	0	0	0	0	0	0
22	F	1	1	3	3	2	2	0	0	1	1
23	F	1	1	2	2	1	1	1	1	2	2
28	F	1	1	2	2	0	0	1	1	0	0
29	F	*	*	3	3	4	4	3	3	3	3
30	M	0	0	2	2	2	2	2	2	2	2
32	F	1	1	3	3	2	1	2	1	1	1
34	F	2	2	2	2	2	3	2	3	2	2
Mean score		1.0	1.0	1.7	1.7	1.2	1.2	1.0	1.0	0.9	1.0
(n)		(33)	(33)	(35)	(35)	(34)	(34)	(34)	(34)	(34)	(34)
Mean score all finishers		0.9	1.0	1.7	1.7	1.2	1.2	1.0	1.0	0.9	1.0
(n)		(32)	(32)	(34)	(34)	(34)	(34)	(34)	(34)	(34)	(34)

* Subjects unable to attend screening, inactive shampoo posted on Day -14.