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Report on tests for the determination of the substantivity
of Octopirox^R on the scalp

Summary .

After two successive shampoos under practical conditions with Octopirox-containing shampoo, the amount of Octopirox that is bound substantively to skin and hair after rinsing with tap water was determined. This amount is equivalent to the difference between the applied and rinsed-off amount of Octopirox.

The investigations produced the following results:

<u>Concentration of Octopirox in shampoo</u>	<u>Amount of Octopirox bound substantively to hair and scalp</u>
0.2 % (w/w)	approx. 4 ± 1 mg
0.5 % (w/w)	approx. 16 ± 4 mg
1.0 % (w/w)	approx. 20 ± 5 mg

In additional tests with subjects who agreed to shave their head, the amount of Octopirox was determined which is adsorbed (only) on to the scalp when using a shampoo with 0.5 % (w/w) Octopirox. The amount was on average 2.5 ± 1 mg, i.e. 10 - 20 % of the amount normally bound substantively to hair and scalp. Already with a hair length of 1.5 cm, the substantively bound amount increased markedly and was on average 13 ± 3 mg in these subjects.

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Tests for the determination of the substantivity of Octopirox^R
on hair and scalp

- Test subjects: (1) Male subjects with normal hair-style
Length of hair 5 to max. 10 cm - Nos. 1 - 10
- (2) Male subjects with shaven head
Length of hair \leq 1 mm - Nos. 11 - 12

Test material: Octopirox-containing shampoo of the following composition:

Fatty alcohol ether sulphate	60.0 % (w/w)
Coconut fatty acid diethanolamide	3.0
Octopirox	0.2 - 1.0
Sodium chloride	q.s.
Perfume oil	q.s.
Water	ad 100.0

pH 8 - 8.5

Procedure

Shampooing was carried out in the usual manner after a weighed amount of shampoo (approx. 4 - 5 g) had been applied on the wet but no longer dripping hair. After about 1 - 2 minutes, the hair was rinsed with 3 litres of lukewarm tap water (40 - 45 °C). The rinsing water was quantitatively collected in stainless steel containers. This shampooing procedure was repeated, but rinsing was done with 6 litres of water.

The amount of Octopirox bound substantively to hair and scalp is the difference between the amount of Octopirox applied for the shampoo and the content of Octopirox in the 9 litres of rinsing fluid.

Period of test: March - December 1976

Analytical methods: UV spectrophotometric determination of the Octopirox-ferric complex.

Detection limit: 0.2 ppm

See report dated 17.12.76 by D. Damm and P. Haidú.

Test subject no.	Analytically determined concentration of Octopirox in the shampoo in % (w/w)	Applied amount of shampoo in g (sum of the two weighed amounts)	Applied amount of Octopirox in mg	Content of Octopirox in 9 litres of rinsing water in mg (mean value of 3 measurements)	Octopirox bound substantively to scalp and hair in mg	Mean value $\bar{x} \pm SD$
1	1.0	8.7	87.0	72.0	15.0	18.3 \pm 4
2	1.0	11.6	116.0	94.5	21.5	
3	0.55	8.5	46.75	28.8	17.95	16.5 \pm 4
4	0.55	7.4	40.7	28.8	11.9	
5	0.55	10.6	58.3	38.7	19.6	
6	0.48	11.1	53.28	40.8	12.48	15.1 \pm 3
7	0.48	12.0	57.6	39.9	17.7	
8	0.18	8.4	15.12	12.6	2.52	3.6 \pm 1
9	0.18	10.7	19.26	14.4	4.86	
10	0.18	8.9	16.02	12.6	3.42	

Subjects with shaven head; 4 days after shaving; length of hair \leq 1 mm

11 a	0.46	9.35	43.0	41.4	1.6	2.5 \pm 1
12 a	0.46	8.15	37.5	34.2	3.3	

The same subjects 46 days after shaving of head; length of hair meanwhile about 1.5 cm

11 b	0.45	7.5	33.7	22.5	11.2	13.2 \pm 2
12 b	0.45	7.95	35.8	20.7	15.1	