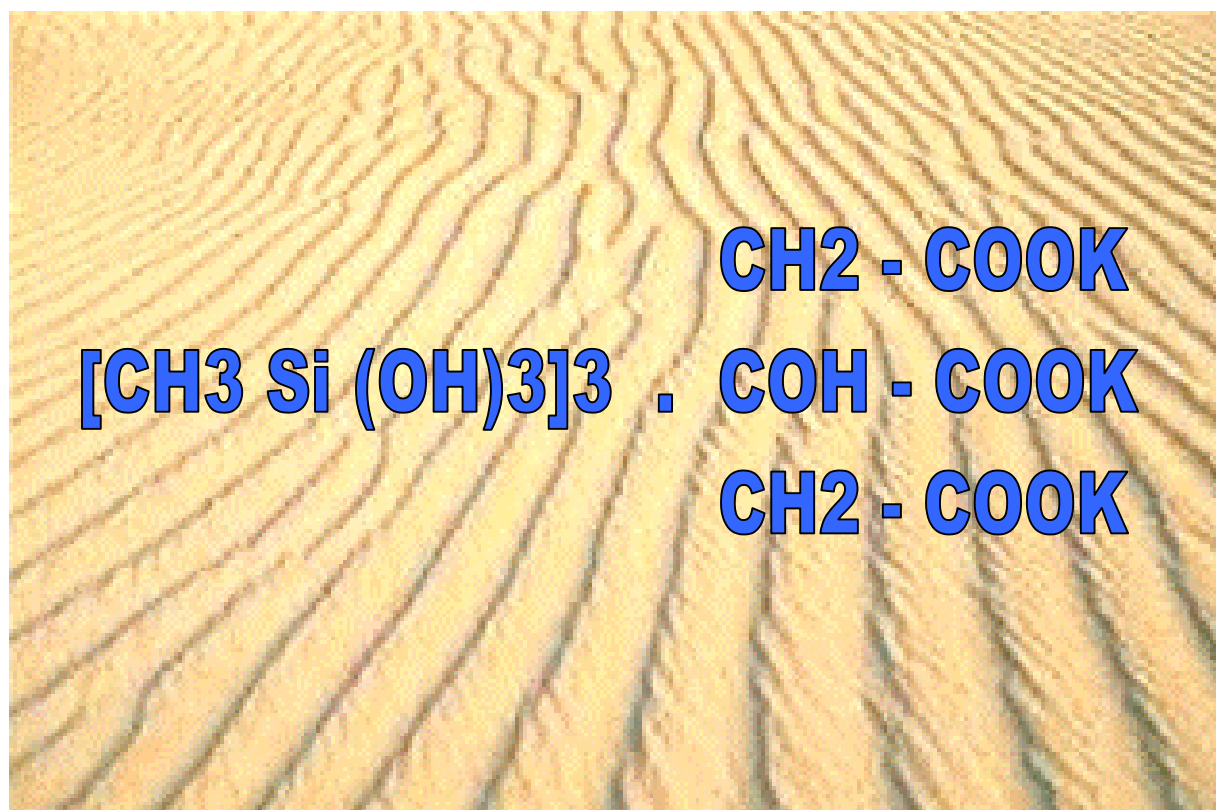




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LABORATOIRES
PROD'HYG

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CONCENTRATED

PRODHYHAIR

SUMMARY

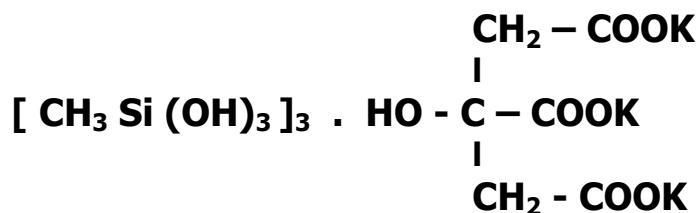
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INTRODUCTION

Silicone is a world wide sprayed molecule representing 26 % of the earth crust but its non-water soluble characteristics made it really unattractive for the biochemist until the early 60's. One of the main researches was to find a way to make Silicon water-soluble in a large quantity. When it has been achieved the results weren't as good as expected and the solubility of the Silicon was very low.

Concentrated Prodhair has been developed in a genuine and patented way to make it water-soluble at a high concentration.

This compound silicon based is part of the Silanol family and presenting a molecular complex of monomethylsilanetriol and potassium citrate as:



Through various clinical studies it has been demonstrate that the Silanol can play an active part in cosmetic formulations as :

BABY AND SENSITIVE Skin product
Softening formulation

COLLAGEN AND SKIN REGENERATOR
Anti-wrinkle formulation

SKIN RESTRUCTURATION
Bust and body shape

The present booklet is showing the activity of **Concentrated Prodhyhair** for the following application:

HAIR TREATMENT

Anti hair-loss and re-growth activity

CONCENTRATED PRODHYHAIR

I. Data sheet

- 1 - Adress

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 16, RUE DES OSIERS
 78310 COIGNIERES
 FRANCE
 TEL : 00 - 33 - (0)1 - 30 - 05 - 07 - 10
 FAX : 00 - 33 - (0) 1 - 34 - 61 - 23 - 87

- 2 - General characteristics

- 2.1. - Chemical description

Monométhylsilanetriol, potassium citrate with carboxylic hydrogel.

- 2.2. - Raw materials

Végétal	Lauric acid, citric acid
Synthetic	Carbomer
Minéral	Silica
Inorganic	Potassium

- 3 - Composition

Potassium citrate silanetriol	10 ± 3 %
Carbomer	2 ± 1 %
Laureth-11	1 ± 1 %
Water	87 ± 5 %

- 4 - Regulation

CAS	EINECS
-	-
866-84-2	212-755-5
9003-01-4	-
9002-92-0	-
7732-18-5	231-791-2

- 5 - Dénomination

I.N.C.I.	C.T.F.A.	JAPON
SILANETRIOL	SILANETRIOL	-
POTASSIUM CITRATE	POTASSIUM CITRATE	-
CARBOMER	CARBOMER	CARBOXYVINYL POLYMER
LAURETH-11	LAURETH-11	POLYOXYETHYLENE
		LAURYL ETHER
AQUA	WATER	WATER

- 6 – Manufacturing process

Acido-basic reaction in aqua with pH control.

- 7 - Quality control data

(Data certified for each batch)

- 7.1. - Organoleptic characters

Appearance	Gel
Colour	Opalescent white
Odour	Slight

- 7.2. - Physico-chemical characteristics

Purity (%)	7.7 ± 0.5
pH (10% in water)	5.0 - 6.8

- 7.3. - Additional descriptive data

(Statistical data not determined regularly for each batch)

Organic silica content (%)	1,2 ± 0.2
----------------------------	-----------

pH FORMULATION 5.0 - 6.8

Keep in dry storage at temperature between 4°C and 35°C.

Do not store under 0°C

- 8 - Impurities

(Statistical data not determined regularly for each batch)

	Unavailable data	Not use during the process	Concentration
Heavy metals			(In determination)
Free ethylene oxyde		X	
Pesticides		X	

- 9 - Specifications concerning impurities

	Méthod	détection
Heavy metals	Ph. Eur III	

- 10 - Stabilizing and auxiliary additives

- 10.1.- Preservative SODIUM METHYL PARABEN : 0.2%

- 10.2.- Antioxydant None

- 10.3.- Other None

- 11 - Bacteriological information

Germ contents	< 100 CFU/g
Pathogen germs	None
Moulds	None
Yeasts	None

- 12 - Biodegradability

Unavailable data

- 13 - Aquatic toxicity

Unavailable data

- 14 - Toxicological information

Unavailable data

This sheet completes the technical data sheet, but does not take place of it. The indications are based on our knowledge at the indicated date. Take care of the eventual risk if the product is used for non previous use.

II. The Hair Kinetic

1. The Hair Cycle

The hair cycle is divided in three steps :

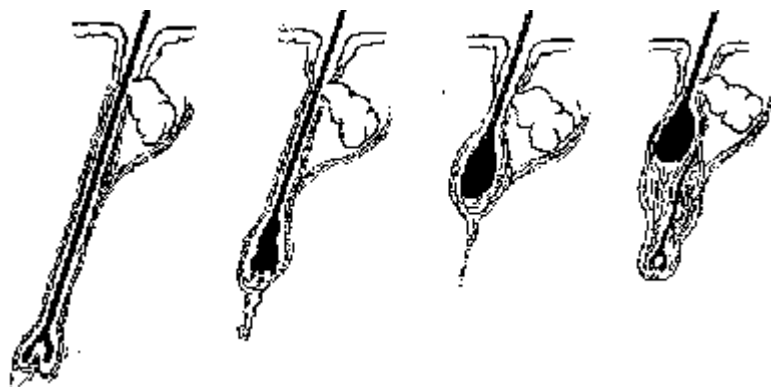
- **ANAGEN** (6 to 36 months) Womb activity : the follicles are growing deep on the scalp. There is an intense metabolism action producing keratin and melanin. The regenerating activity is high.

- **CATAGEN** (2 weeks) Transition phase: the hair bulb is shorter and thinner. The hair is mature. An increasing number of hair at this stage is the first symptom of a growing alopecia.

- **TELOGEN** (3 months) Fading hair: the follicle is even shorter and the bulb is rising at the top of the skin until its fall. On a daily basis we are loosing 60 to 100 hairs per day.

During an androgenic alopecia the number of hair at this stage is increasing dramatically.

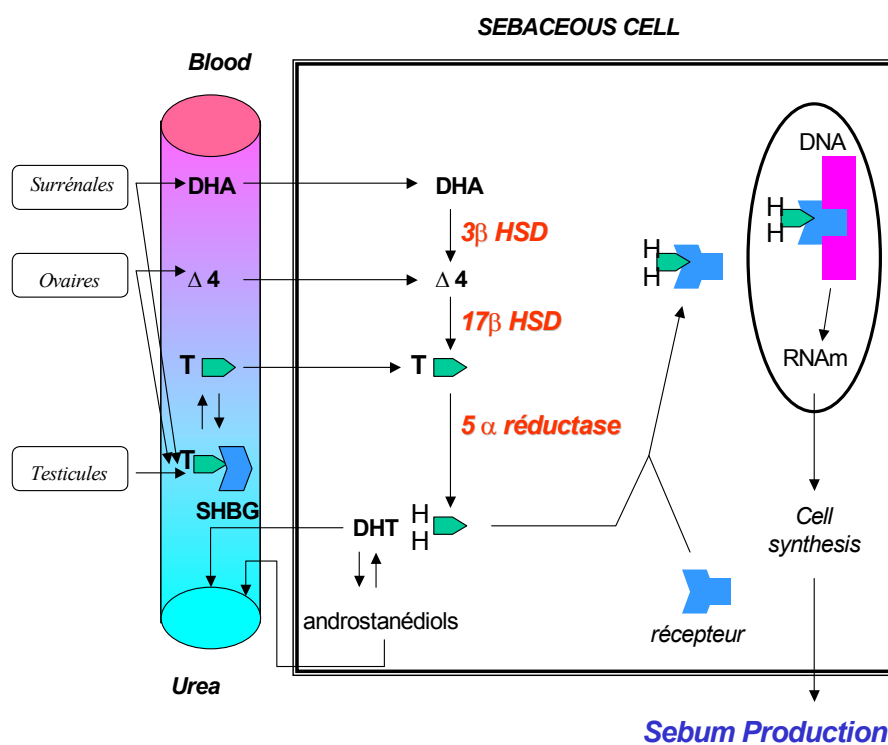
ANAGEN CATAGEN TELOGEN



2. Androgenic Alopecia

The following studies will show how the **Concentrated Prodyhair** is working to reduce an hyper-seborrhoea where an androgenic hairless is taking place.

The androgenic hormones are working as follow in the sebaceous cell, their role is to create sebum



<u>Hormones</u>	DHA	dihydroépiandrostérone
	$\Delta 4$	$\Delta 4$ -androstènedione
	T	testostérone
	DHT	dihydrotestostérone
<u>SHBG</u>		Sexual Hormone Binding Globulin
<u>Enzymes</u>	3β HSD	3β -hydroxystéroïde-déshydrogénase
	17β HSD	17β -hydroxystéroïde dehydrogénises
	5α réductase	5α reductive

The active form of the androgen is the **DHT**, this hormone is produce by the reaction of the testosterone and the enzyme : **5α -réductase**.

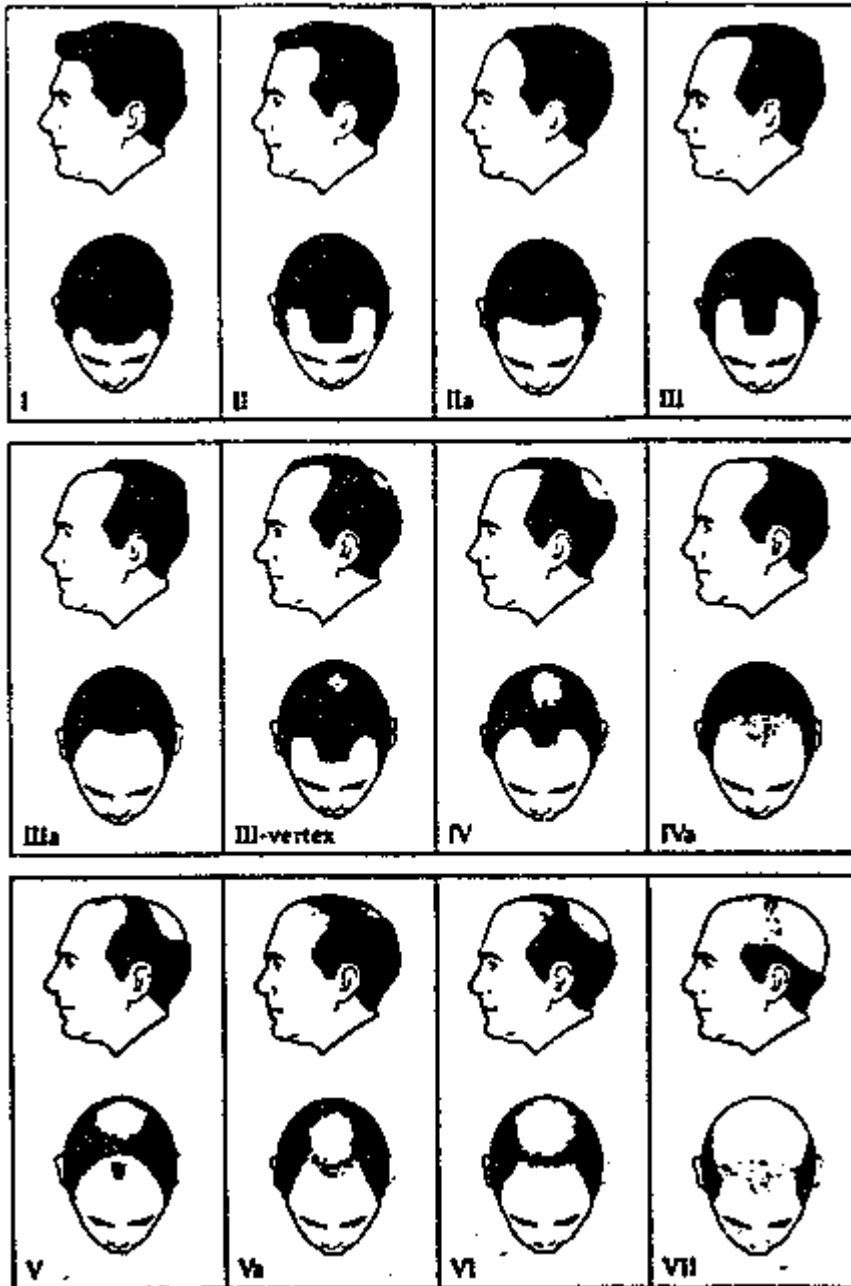
During the Anagen phases, the 5α -réductasique activity is very high on the scalp area. It has been demonstrate that during an androgenic alopecia, the 5α -réductasique activity is even greater.

Its mean that an over activity of the sebaceous cell and an over production of sebum is one of the root cause of an Androgenic alopecia.

3. The Hamilton classification

The various stages of Alopecia and the Hamilton classification.

The simplified Hamilton chart is used to scientifically classify and quantify the various stages of alopecia.



LABORATORY AND CLINICAL TEST

The anti Hair loss and re-growth activities of the **Concentrated Prodhyhair** have been demonstrate through two clinical tests: a planimetric study and a trichogram count. Further microscopic observation did help to compare the shape of the hair before and after the treatment.

III. Panimetric studies

1. Panel description

Population 30 peoples
 Ages 23 to 59
 Details 2 women 48 and 56 years old
 28 men, 23 to 59 years old

2. Trial

The product tested is :

A lotion:	PRODHYHAIR CONCENTRE	20.0 %
	Water	80.0 %
A Shampoo:	PRODHYHAIR CONCENTRE	0.6 %
	Soft surfactant	33.0 %
	Water	66.4 %

Frequency:

- On a daily basis, use of the lotion on the scalp with a light massage during 1 to 2 minutes.
- Twice a week, use of the shampoo.

3. Protocol

Each individual is numbered from 1 to 30.
 Planimetric measurements are made as follow:

A celluloid sheet is applied on the scalp of each person and the alopecia area is draw and calculates in square centimetres.

The planimetric measurement are made at T0 (1 day before the treatment) and at T240 (240 days after the beginning of the treatment)

4. Clinical Observations

The following charts show the result of the observations :

S0 Area (in square cm) measured before the treatment at T0
 S240 Area (in square cm) measured after the treatment at T240

CLINICAL OBSERVATIONS

N°	S0 Area at T0	S240 Area at T240	% Regrowth at T240
1	22	25	0,0 %
2	26	0	100,0 %
3	16	0	100,0 %
4	83	38	54,2 %
5	13	0	100,0 %
6	34	0	100,0 %
7	145	140	3,4 %
8	55	29	47,3 %
9	55	5	90,9 %
10	252	253	0,0 %
11	125	66	47,2 %
12	170	95	44,1 %
13	156	38	75,6 %
14	56	0	100,0 %
15	37	3	91,9 %
16	180	17	90,6 %
17	205	120	41,5 %
18	180	99	45,0 %
19	306	298	2,6 %
20	157	79	49,7 %
21	231	142	38,5 %
22	133	68	48,9 %
23	117	48	59,0 %
24	51	51	0,0 %
25	48	0	100,0 %
26	235	235	0,0 %
27	45	3	93,3 %
28	47	3	93,6 %
29	19	19	0,0 %
30	179	179	0,0 %
S (cm²)	3378	2053	
Number	30	30	
Average	112,60	68,43	53,92 %

5. Results

a Planimetric results

0 < % re-growth < 10 %

6 peoples 20 % of the population
 2 peoples 6,6 %

insignificant result
 light increase of the thin hair

10 < % growth < 90 %

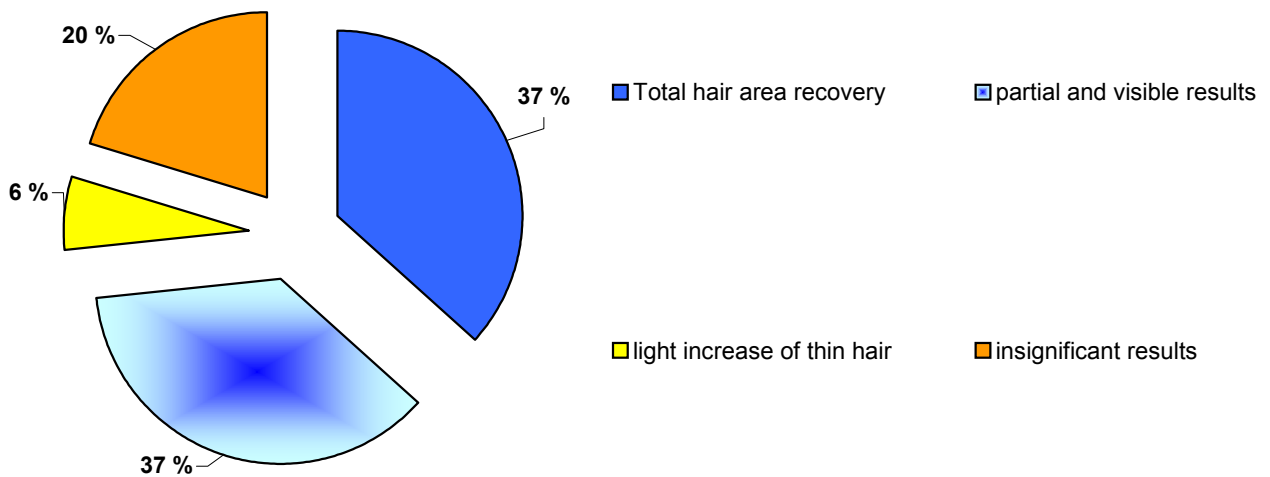
11 peoples 36,7 %

partial and visible results

90 < % growth < 100 %

11 peoples 36,7 %

total recovery hair area

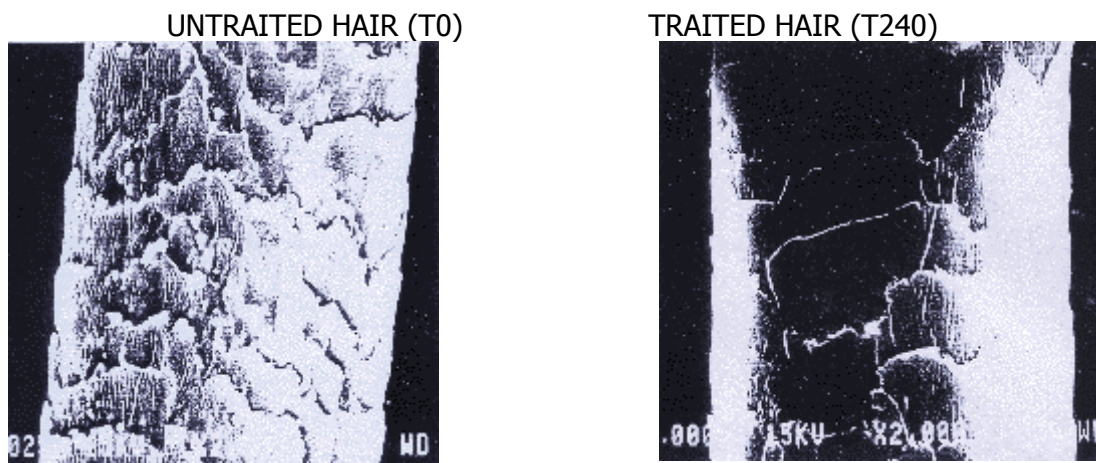


b Complementary clinical observations

- The hair loss is stopped from one to four weeks after the beginning of the treatment.
- The hyper-seborrhoea is reaching a normal level.
- The last areas where the hair loss appears are the one, which recover first.
- The thin hairs are transformed in mature and strong ones.
- The re-growth activity takes place from 20 to 90 days after the beginning of the treatment.

6. Microscopic observation

A morphologic comparison of two hairs before and after the treatment (240 days) with **CONCENTRED PRODHYHAIR** is done with microscopic observations.



The treated Hair is presenting:

- Squarer scales at the roots
- Free and natural ends.

7. Conclusion

This planimetric study shows that after 240 days of treatment with **CONCENTRATED PRODHYHAIR**, the androgenic alopecia is diminished and the hair are healthier and are re-growing in most of the case. This study shows:

A real efficiency of the CONCENTRED PRODHYHAIR for androgenic alopecia.

IV. Trichograms

1. Panel description

Population 45 peoples
 Ages 29 to 61
 Details 15 women (26 to 50)
 30 men (22 to 49)

2. Trial

The product used is a lotion made of: **CONCENTRATED PRODHYHAIR** 6.0 %
 Water 84.0 %

On a daily basis each people use:

- 5 ml of the previous lotion on the scalp at the roots area.
- Light massage to disperse the lotion and make it penetrate.

Trichograms are count at: T0 day (before treatment)
 T150 days (after treatment)

3. Protocol

Each people are numbered from 1 to 45.

Volunteers are presenting androgenic alopecia with hyper seborrhoea (87 % of the world wide hair loss) with more than 35 % of the follicles in Telogen stage.

People with alopecia due to stress, diseases or chemical treatment have not been taken for this test; these cases usually are curing by themselves as soon as the causes (illness, medicine, stress...) are no more present.

4. Count

The hairs are taken with round-ended claws protected with rubber ends to not damaged the hair. 60 hairs are taken at T0 and another 60 are taken at T150 at the end of the study.

Right after the pull, the hair is studied and their roots are measured with a microscope. The numbers of hair in the different stages (Anagen; Catagen; Telogen) are count at T0 and at T150.

5. Results

A0 Nb of hair in Anagen at T0 before treatment
 C0 Nb of hair in Catagen at T0 before treatment
 T0 Nb of hair in Telogen at T0 before treatment

A1 Nb of hair in Anagen at T150 after treatment
 C1 Nb of hair in Catagen at T150 after treatment
 T1 Nb of hair in Telogen at T150 after treatment

A/T	Ratio	$\frac{\text{Number of hair in Anagen phase}}{\text{Number of hair in Telogen phase}}$	(A/T = 4 is the average)
-----	-------	--	--------------------------

6. Clinical observations

N°	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
AGE	27	45	33	37	34	27	37	32	30	41	27	30	32	49	30
SEX	H	F	F	F	F	F	H	H	H	H	H	H	F	H	H
TYPE	3	D	D	D	D	3	3	3	3	4	2	3	D	4	2
HYPERSEBORRHEE	AV	AV	AV	AV	AV	Strong	AV	Strong	Strong	Normal	AV	Strong	AV	Strong	Strong
A0	37	38	37	39	35	38	38	36	38	34	39	37	35	36	37
% A0	61,67	63,33	62,71	65,00	58,33	63,33	63,33	60,00	63,33	57,63	65,00	61,67	59,32	60,00	61,67
A1	50	54	49	55	51	57	57	52	47	54	48	52	44	48	48
% A1	83,33	90,00	81,67	91,67	85,00	95,00	95,00	86,67	78,33	90,00	80,00	86,67	73,33	80,00	80,00
C0	0	0	0	2	1	1	1	0	1	1	0	0	1	0	1
% C0	0,00	0,00	0,00	3,33	1,67	1,67	1,67	0,00	1,67	1,69	0,00	0,00	1,69	0,00	1,67
C1	0	0	0	0	1	0	0	0	0	1	0	0	1	0	0
% C1	0,00	0,00	0,00	0,00	1,67	0,00	0,00	0,00	0,00	1,67	0,00	0,00	1,67	0,00	0,00
T0	23	22	22	19	24	21	21	24	21	24	21	23	23	24	22
% T0	38,33	36,67	37,29	31,67	40,00	35,00	35,00	40,00	35,00	40,68	35,00	38,33	38,98	40,00	36,67
T1	10	6	11	5	8	3	3	8	13	5	12	8	15	12	12
% T1	16,67	10,00	18,33	8,33	13,33	5,00	5,00	13,33	21,67	8,33	20,00	13,33	25,00	20,00	20,00
A0 / T0	1,61	1,73	1,68	2,05	1,46	1,81	1,81	1,50	1,81	1,42	1,86	1,61	1,52	1,50	1,68
A1 / T1	5,00	9,00	4,45	11,00	6,38	19,00	19,00	6,50	3,62	10,80	4,00	6,50	2,93	4,00	4,00
ANTI-HAIR LOSS ACTIVITY															
ANTI HAIR LOSS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Light re-growth	Light	3	Light	3	2	Yes	3	2	0	3	Yes	3	0	3	1
Hair Growth	0	3	1	3	2	3	3	1	0	2	NO	1	0	0	0
No answer	-	-	-	-	-	-	-	-	Yes	-	-	-	Yes	-	-

N°	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
AGE	31	38	40	35	25	27	25	33	27	39	28	41	40	29	30
SEXE	H	F	F	F	H	H	H	H	H	F	H	H	H	H	H
TYPE	4	D	D	D	2	2/3	2/3	2	4	D	3	3	2	4	3
HYPERSEBORRHE	Strong	Av	Strong	Av	Strong	Av	Strong	Strong	Strong	Av	Strong	Av	Av	Strong	Strong
A0	35	35	39	38	35	34	35	34	35	39	38	38	36	32	32
% A0	58,33	59,32	65,00	63,33	58,33	58,62	58,33	56,67	58,33	65,00	63,33	63,33	61,02	56,14	56,14
A1	36	50	50	47	56	51	50	52	51	50	50	50	56	50	50
% A1	66,67	83,33	83,33	78,33	93,33	85,00	83,33	86,67	85,00	83,33	83,33	83,33	93,33	83,33	83,33
C0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	1
% C0	0,00	0,00	0,00	0,00	0,00	1,72	1,67	0,00	0,00	0,00	0,00	0,00	0,00	1,75	1,75
C1	0	0	0	0	0	1	2	0	1	0	1	0	0	0	0
% C1	0,00	0,00	0,00	0,00	0,00	1,67	3,33	0,00	1,67	0,00	1,67	0,00	0,00	0,00	0,00
T0	25	24	21	22	25	23	24	26	25	21	22	22	23	24	24
% T0	41,67	40,68	35,00	36,67	41,67	39,66	40,00	43,33	41,67	35,00	36,67	36,67	38,98	42,11	42,11
T1	18	10	10	13	4	8	8	8	8	10	9	10	4	10	10
% T1	33,33	16,67	16,67	21,67	6,67	13,33	13,33	13,33	13,33	16,67	15,00	16,67	6,67	16,67	16,67
A0 / T0	1,40	1,46	1,86	1,73	1,40	1,48	1,46	1,31	1,40	1,86	1,73	1,73	1,57	1,33	1,33
A1 / T1	2,00	5,00	5,00	3,62	14,00	6,38	6,25	6,50	6,38	5,00	5,56	5,00	14,00	5,00	5,00
<u>Anti Hair loss activity</u>															
Anti Hair loss	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Light re-growth	0	3	2	0	3	3	3	2	2	2	2	2	3	2	2
Hair re-growth	0	1	2	0	3	2	2	0	0	0	1	1	2	1	0
No Answer	Yes	-	-	Yes	-	-	-	-	-	-	-	-	-	-	-

N°	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
AGE	30	34	40	33	49	50	28	36	26	25	31	22	24	41	42
SEXE	M	M	M	F	F	F	M	M	F	M	M	M	M	F	M
TYPE	3	3	4	D	D	1	1	1	2	2	3/4	2	3	D	3
HYPERSEBORRHEE	Strong	Av	Light	Av	Av	Light	Norm	Norm	Light	Strong	Norm	Strong	Strong	Light	Light
A0	38	37	36	34	35	39	38	38	39	37	35	37	39	37	36
% A0	65,00	61,67	60,00	56,67	58,33	65,00	63,33	64,41	65,00	61,67	58,33	61,67	65,00	61,67	60,00
A1	53	42	43	51	53	49	41	52	55	46	49	53	53	50	48
% A1	81,67	70,00	71,67	85,00	88,33	81,67	64,06	86,67	91,67	76,67	81,67	88,33	88,33	83,33	80,00
C0	0	1	0	1	0	0	0	0	0	0	1	1	0	1	1
% C0	0,00	1,67	0,00	1,67	0,00	0,00	0,00	0,00	0,00	0,00	1,67	1,67	0,00	1,67	1,67
C1	0	0	1	0	0	1	1	1	0	0	0	0	0	0	1
% C1	1,67	0,00	1,67	0,00	0,00	1,67	1,56	1,67	0,00	0,00	0,00	0,00	0,00	0,00	1,67
T0	22	22	24	25	25	21	22	21	21	23	24	22	21	22	23
% T0	35,00	36,67	40,00	41,67	41,67	35,00	36,67	35,59	35,00	38,33	40,00	36,67	35,00	36,67	38,33
T1	7	18	16	9	7	10	22	7	5	14	11	7	7	10	11
% T1	16,67	30,00	26,67	15,00	11,67	16,67	34,38	11,67	8,33	23,33	18,33	11,67	11,67	16,67	18,33
A0 / T0	1,86	1,68	1,50	1,36	1,40	1,86	1,73	1,81	1,86	1,61	1,46	1,68	1,86	1,68	1,57
A1 / T1	4,90	2,33	2,69	5,67	7,57	4,90	1,86	7,43	11,00	3,29	4,45	7,57	7,57	5,00	4,36
<u>Anti Hair Loss Activity</u>															
Anti Hair Loss	Yes	c	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Light regrowth	3	0	0	2	3	2	0	3	3	0	1	2	2	1	0
Hair Regrowth	3	0	0	2	2	2	0	2	3	0	0	1	1	0	0
No answer	-	Yes	Yes	-	-	-	Yes	-	-	Yes	-	-	-	-	-

7. Results

The measurements have been done at T0 day before treatment
T150 days after treatment

In the following chart shows the different groups of trichograms ratio results.

8 individuals, $A1/T1 < 4$ 18 %

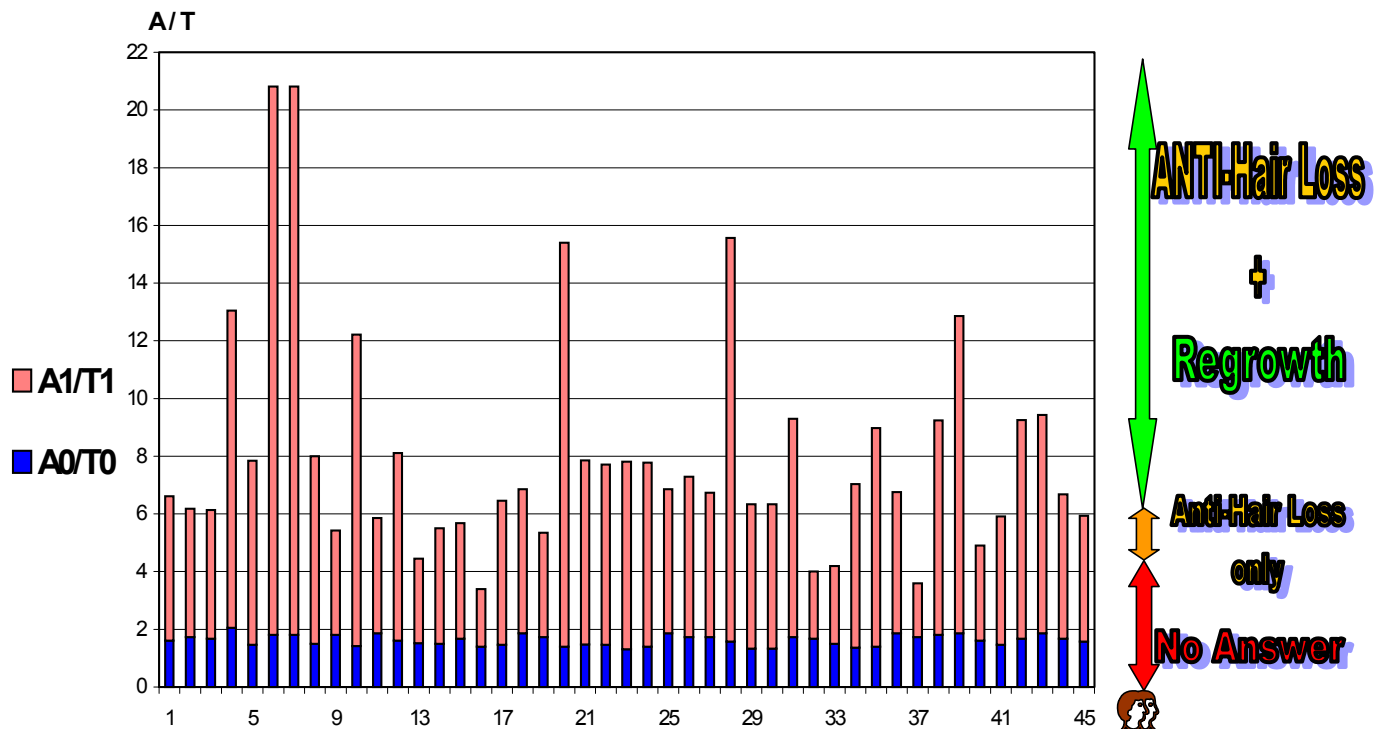
For these peoples, it seems that the treatment did not work, even if the Ratio $A1/T1$ is greater than $A0/T0$ the natural sebum regulation is not balanced and is still in excess.

7 individuals, $4 < A1/T1 < 5$ 16 %

For the peoples where the ratio is in between 4 and 5, the clinical observation shows the stop of the Hair loss and the beginning of a re-growing activity for the thin hair.

30 individuals, $A1/T1 > 5$ 66 %

For these peoples the $A1/T1$ is over 5. The clinical observation shows the anti hair loss activity and the re-growth of the hair.



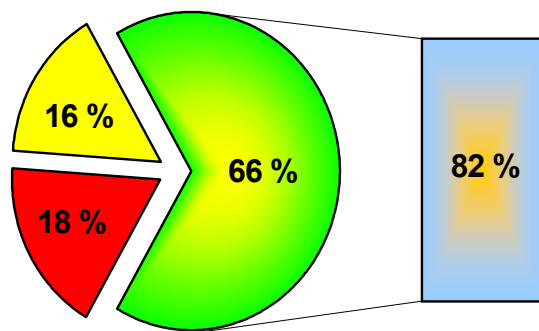
8. Conclusion

Two main groups of positive result have been observed.

- **The whole recovery of the alopecia area.**
- **A progressive recovery starting from the latest bald zone.**

No correlation have been establish between the age, the sex or the quantity of the hair-loss area.

This study shows that for 16% of the cases **CONCENTRED PRODHYHAIR** stop the hair-loss only. For 66% of the treated cases the stop of the hair-loss is combined with the recovery of the hair.



No answer **18 %**

Anti-Hair Loss Activity Only 16 %

ANTI-HAIR LOSS + RE-GROWTH **66 %**

**For your Hair-Treatment
Formulation**

CONCENTRED PRODHYHAIR

EFFICIENT at more than 80 %

COSMETIC APPLICATIONS

The silanol activity is well documented in the scientific literature. Combined with the above clinical test, the **CONCENTRED PRODHYHAIR** utility is highlighted.

Function:

- Elastin and collagen biosynthesis increaser.
- Mitochondria activity and cell multiplication booster
- Positive action the metabolism of the Calcium, Phosphorus and magnesium ions.

Efficiency

- Derma regeneration.
- Decrease of the scalp inflammation due to hyper-seborrhoea
- Improvement of the scalp microcirculation.

Cosmetic application

- Following these observation we can state that:

CONCENTRED PRODHYHAIR

Distribute a real and reproducible efficiency for:

CAPILLAR RESTRUCTURATION

ANTI HAIR LOSS ACTIVITY

HAIR RE-GROWTH ACTIVITY

FORMULATIONS

HAIR LOTION

REF LCPC01

CONCENTRATED PRODHYHAIR	Active ingredient	10.0
WATER	Solvent	89.0
HYDROLIZED SWEET ALMOND PROTEIN	Additive	1.0
PRESERVATIVE	Preservative	Q.S.
FRAGRANCE	Fragrance	Q.S.

SOFT SHAMPOO

REF SDPC01

LAURYL GLUCOSIDE	Surfactant	8.0
COCAMIDOPROPYL BETAINE	Surfactant	27.0
XANTHAN GUM	Thickener	1.0
WATER	Solvent	61.0
CONCENTRATED PRODHYHAIR	Active ingredient	3.0
PRESERVATIVE	Preservative	Q.S.
FRAGRANCE	Fragrance	Q.S.

SPRAY HAIR LOTION

REF LSPC02

POLYQUATERNIUM-7	Conditionner	2.0
LAMESOFT PO 65	Additive	2.0
CONCENTRATED PRODHYHAIR	Active ingredient	3.0
WATER	Solvent	93.0
PRESERVATIVE	Preservative	Q.S.
FRAGRANCE	Fragrance	Q.S.

STYLING FOAM

REF SMPC01

WATER	Solvent	93.6
CHITOSAN	Additive	1.0
GLYCOLIC ACID	Solubilizer	0.4
POLYQUATERNIUM-7	Conditionner	1.0
CETRIMONIUM CHLORIDE	Conditionner	1.0
CONCENTRATED PRODHYHAIR	Active ingredient	3.0
PRESERVATIVE	Preservative	Q.S.
FRAGRANCE	Fragrance	Q.S.

STYLING GEL

REF SGPC01

WATER	Solvent	42.0
POLYQUATERNIUM-7	Conditionner	2.0
VEGETAL OIL	Solvent	10.0
OLETH-10	Surfactant	20.0
PEG-40 HYDROGENATED CASTOR OIL	Solubilizer	10.0
PROPYLENE GLYCOL	Solvent	7.0
GLYCERINE	Solvent	6.0
CONCENTRATED PRODHYHAIR	Active ingredient	3.0
PRESERVATIVE	Preservative	Q.S.
FRAGRANCE	Fragrance	Q.S.

PRODHYHAIR CONCENTRE must be include in formulation at ph between 5,0 et 6,8.

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