REPORT

Nr. CTE249C/R
Final version

Title of study: **Evaluation of the efficacy of a food supplement in reducing hair loss. 8-week monocentric cosmetic efficacy study on 21 healthy Caucasian male and female volunteers.**

Dates of study: October 19 to December 17, 2015

Test preparations: 1 food supplement (powder) delivered by the Sponsor

Product code (STI)	Description	Product code (Sponsor)
P	Food supplement	S-577

Study nr. **CTE249A**

Date (Report): December 18, 2015

Sponsor:
Mibelle Biochemistry
Bolimattstrasse 1
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THIS DOCUMENT IS CONFIDENTIAL

This document contains 15 pages and 4 Appendices

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Study Centre – Responsibilities

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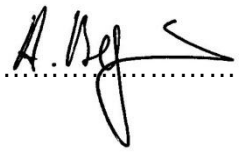
Authentication

I confirm with my signature that this study was performed under my supervision. The principles of Good Clinical Practice were taken as a guide of reference for the conduct of this study.

Investigator and Author of the report:

Alain Béguin, PhD



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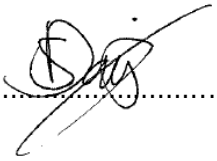
This report constitutes a true and faithful account of the procedures adopted and of the results obtained in this study.

Quality Assurance Skin Test Institute:

Sébastien David



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1. STUDY DESIGN

1.1 Title of the study

Evaluation of the efficacy of a food supplement in reducing hair loss. 8-week monocentric cosmetic efficacy study on 21 healthy Caucasian male and female volunteers.

1.2 Aim and summary of conditions

The aim of the study was to evaluate the anti-hair loss properties on the scalp of a food supplement, during 2 months. 1 composition was evaluated **(S-577,** herafter: **P)**. There was no placebo formulation. A total of 3 male and 18 female volunteers took part to the study. The product was taken orally by volunteers once daily at home, during 8 weeks. Approximately 100 mg were taken daily.

1.3 Tested product(s)

1.3.1 Information provided by the Customer:

- Product names: 1 food supplement (powder) delivered by the Sponsor

Product code (STI)	Description	Product code (Sponsor)
P	Food supplement	S-577

- INCI: Pisum Sativum (Pea) Sprout Extract (and) Isomalt (and) Aqua/Water
- The tested cosmetic product does not contain any substance which is forbidden by EEC legislation regarding the use of cosmetic and personal hygiene products. The preservatives in the product formula are in the list of accepted components published by the EEC and are used in a concentration provided for by the law. The substances for which concentration limits exist are used in accordance with limits and instructions published in the Enclosures of the 76/768 EEC regulation and its successive amendments.
- The cosmetic product was evaluated for their safety of use on human volunteers (cosmetic dossier).
- Qualitative INCI formula: filed.

1.4 Ethical requirements

The study was carried out in accordance with the following ethical requirements:

- All the subjects participating in the study are healthy volunteers at least 18 years old.
- All the subjects participating in the study are selected according to inclusion/non inclusion criteria (see respective paragraph “Inclusion criteria” and “Non inclusion Criteria”).
- Volunteer participation in the study is totally free.
- All the subjects participating in the study are informed of the aim and the nature of the study.
- All the subjects participating in the study are informed of the potential risks involved.
- All the subjects participating in the study give their informed consent signed at the beginning of the study.
- Before volunteers are exposed to the product to be tested, all relevant safety information about the product itself and each ingredient was collected and evaluated.
- All the study procedures are carried out in accordance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and successive amendments).
- All necessary precautions are taken to avoid adverse skin reactions.
- If unexpected/adverse skin reactions occur, the severity of the reaction is evaluated and reported in the data collection sheets, and if necessary a dermatologist proceeds with the appropriate therapy.

1.5 Subjects

1.5.1 Enrolment of subjects

The subjects participating in the study were selected from a panel of male and female volunteers in accordance with the following inclusion and non-inclusion criteria:

1.5.2 Inclusion criteria

- Male or female.
- Excessive hair shedding (more than 100 lost hair units daily).
- Phototype I-III.
- Caucasian.
- Age: 18-65 years.
- Healthy with no significant concurrent illness.
- Having signed informed consent form after receiving the volunteer information and after the nature of the study has been fully explained.

1.5.3 Non-inclusion criteria

- Volunteers not matching scalp, respectively hair qualifications above.
- Volunteers not matching the other eligibility criteria above.
- Incorrect ethnic origin.
- Food allergy against legumes
- Participation in any other clinical study/use of experimental drug(s) involving the test areas within the previous 8 weeks.
- Use of any topical (drug containing) or cosmetic product anti-aging purposes on the test areas within 5 days before beginning the study.
- Obvious medical pathologies such as AGA, Alopecia areata, Diffluvium.
- History or evidence of drug and/or alcohol abuse.
- Severe systemic or dermatological disease.
- Impaired cooperation possibilities or unwillingness to satisfactorily participate in the study.
- Other(s), considered as important by the investigator.

1.6 Study execution

After being enrolled in the study (see inclusion and exclusion conditions above) volunteers were requested to collect their daily lost hairs in envelopes as follows: during each hair collection day volunteers had to collect lost hairs on the comb or the brush mornings and evenings.

Volunteers were left free to continue washing their hair during the whole study period according to the usual washing routine and shampoo. The only restriction was a ban of use of other products against hair loss, one month before taking part to the study and during the whole study period.

Hair collection days were defined as follows:

- D0-3 + D0-2 + D0-1, altogether producing the mean baseline hair collection value
- D25 + D26 + D27, altogether producing the mean one-month (D25-D27) hair collection value
- D53 + D54 + D55, altogether producing the mean two-month (D53-D55) hair collection value

At each time point (t0=D0, t1=D28, t2=D56) volunteers brought back the 3 hair collection envelopes. A dermatological assessment was performed visually on the scalp in order to detect any possible intolerance reaction or any scalp or hair issue which would be incompatible with the study continuation.

1.7 Materials and methods

The following materials and methods were used in this study:

1.7.1 Lost hair count

Follow-up of the quantitative hair loss reduction, performed by counting lost hair collected by volunteers once daily (mornings, by combing hair) in envelopes. Collected hair was counted by a trained laboratory technician.

1.7.2 Scalp photographs

Scalp photographs were made at each time point (t0,t1,t2) using a Visioface® device (Courage & Khazaka).

1.7.3 Sensory evaluation questionnaire

A sensory evaluation questionnaire was filled by all volunteers at t2. The main topic of this questionnaire concerned the satisfaction about the performance of treatment and the hair condition.

1.8 Results and statistics

1.8.1 Results

Results are reported in tables. All calculations are done using Microsoft Excel® worksheets.

1) The mean values are calculated as:

$$m = \frac{\sum_{1}^{n} p}{n} \qquad [1]$$

p is the value of parameter to be analyzed of each subject participating to the study and n the number of subjects

2) The standard error of the mean (SEM) is calculated as:

$$SEM. = \frac{\sqrt{\frac{\sum_{1}^{n}(p_i^2) - \frac{\sum_{1}^{n} p_i^2}{n}}{(n-1)}}}{\sqrt{n}} \qquad [2]$$

3) The mean percentage variations are calculated as:

$$\overline{Var(\%)} = \sum_{1}^{b} \frac{p_T - p_0}{p_0} \quad [3]$$

p_o is the value of the parameter before product application;
p_t is the value of the parameter to be analysed after 28 (D28) or 56 (D56) days of product application.

1.8.2 Statistical analysis

Non-parametric permutation analyses were performed on paired data, for all the measured parameters.

2. RESULTS

2.1 Volunteers: Demographic Data

23 male and female volunteers were recruited in this study. One volunteer dropped out at t0 for medical reasons (#5023), and a second volunteer dropped out after 1 month of applications (t1), for professional reasons (#5014). Finally 21 volunteers completed the 56 days of treatment and attended the 3 measurement sessions. The results from 21 volunteers were considered in calculations. The demographic data of all volunteers are summarised in Table 1 below. The demographic calculations skip the data of the dropped out volunteers #5023 and #5014.

An overview of the demographic data of the 21 remaining volunteers gives the following figures:
- 3 male (14%) and 18 female volunteers (86%) participated in the study;
- Among the 18 participants 5 were allergic (28%). See below:

Allergies

Nr.	Vol. Nr.	Allergy
5007	20062	Drug allergy: Penicillin.
5016	19982	Rhinitis allergica (hay fever).
5018	01122	Rhinitis allergica (hay fever).
5021	16302	Rhinitis allergica (hay fever). Contact allergy: Cat's hair.

Table 1 – Demographic data

Nr.	Vol. Nr.	Age (y)	Skin type (face)	Gender	Allergies	Drop out
5001	11951	26.9	combination	m	N	
5002	14532	39.0	very dry	f	N	
5003	20022	44.0	oily	f	N	
5004	18202	46.1	normal	f	N	
5005	14582	58.0	dry	f	N	
5006	19702	50.1	combination	f	N	
5007	20062	26.4	combination	f	Y	
5008	18481	23.9	dry	m	N	
5009	13832	54.1	combination	f	N	
5010	09132	59.1	oily	f	N	
5011	20012	40.5	normal	f	N	
5012	13052	62.5	normal	f	N	
5013	12872	46.6	combination	f	N	
5014	20042	26.7	dry	f	N	x
5015	12821	24.5	oily	m	N	
5016	19982	46.9	combination	f	Y	
5017	07472	49.1	combination	f	N	
5018	01122	50.2	combination	f	Y	
5019	02452	47.4	oily	f	N	
5020	00242	51.8	combination	f	N	
5021	16302	21.6	dry	f	Y	
5022	16292	52.3	normal	f	N	
5023	15452	45.8	normal	f	N	x
Nb. Vol.		**Mean age:**	**normal:**	**male:**	**Allergic:**	**Drop out:**
21		**43.9**	**4**	**3**	**4**	**1**
		Std. dev.	**combination:**	**female:**		
		12.4	**9**	**19**		
		Min. age:	**dry:**			
		21.6	**4**			
		Max. age:	**oily:**			
		62.5	**4**			

2.2 Lost hair assessments (hair counts)

TABLE 2 – Lost hairs were counted from a total of 3x3 envelopes per volunteer during the whole study. Table 1 below indicates the numbers of lost hair counted, the mean values and the variations versus t0 obtained for each volunteer. Units are numbers of lost hair. The original tables of results (EXCEL spreadsheet) have been sent electronically to the Sponsor (Appendix 1).

Vol. Nr.	D0-3	D0-2	D0-1	Baseline (means)	D25	D26	D27	D25-D27 (means)	%-difference 1 month	D53	D54	D55	D53-D55 (means)	%-difference 2 months
5001	146	137	135	139.3	20	44	52	38.7	-72.2%	16	16	12	14.7	-89.5%
5002	107	256	115	159.3	60	300	41	133.7	-16.1%	223	63	90	125.3	-21.3%
5003	340	270	274	294.7	120	60	150	110.0	-62.7%	180	127	225	177.3	-39.8%
5004	151	125	121	132.3	70	60	165	98.3	-25.7%	75	103	54	77.3	-41.6%
5005	132	212	242	195.3	214	126	180	173.3	-11.3%	109	128	125	120.7	-38.2%
5006	103	101	116	106.7	18	41	24	27.7	-74.1%	18	28	14	20.0	-81.3%
5007	117	43	140	100.0	120	62	83	88.3	-11.7%	125	66	77	89.3	-10.7%
5008	200	200	220	206.7	181	160	200	180.3	-12.7%	130	180	58	122.7	-40.6%
5009	250	172	212	211.3	98	124	121	114.3	-45.9%	138	146	130	138.0	-34.7%
5010	142	120	88	116.7	122	135	116	124.3	6.6%	90	127	100	105.7	-9.4%
5011	183	56	118	119.0	60	74	147	93.7	-21.3%	87	120	108	105.0	-11.8%
5012	75	147	185	135.7	136	105	144	128.3	-5.4%	145	73	142	120.0	-11.5%
5013	143	65	110	106.0	120	63	90	91.0	-14.2%	40	54	29	41.0	-61.3%
5015	110	124	150	128.0	47	41	35	41.0	-68.0%	69	70	71	70.0	-45.3%
5016	163	185	147	165.0	84	50	29	54.3	-67.1%	33	70	13	38.7	-76.6%
5017	107	68	266	147.0	37	270	45	117.3	-20.2%	49	120	36	68.3	-53.5%
5018	37	237	305	193.0	199	65	323	195.7	1.4%	194	42	302	179.3	-7.1%
5019	230	200	135	188.3	50	60	50	53.3	-71.7%	65	110	43	72.7	-61.4%
5020	80	100	100	93.3	45	30	40	38.3	-58.9%	130	31	64	75.0	-19.6%
5021	172	164	178	171.3	170	112	170	150.7	-12.1%	270	330	150	250.0	45.9%
5022	322	335	330	329.0	110	225	165	166.7	-49.3%	125	150	20	98.3	-70.1%
Mean value				163.7				105.7	-33.9%				100.4	-37.1%
Standard deviation				61.2				50.6					56.2	
p value [1]				–				0.0000 ***					0.0002 ***	

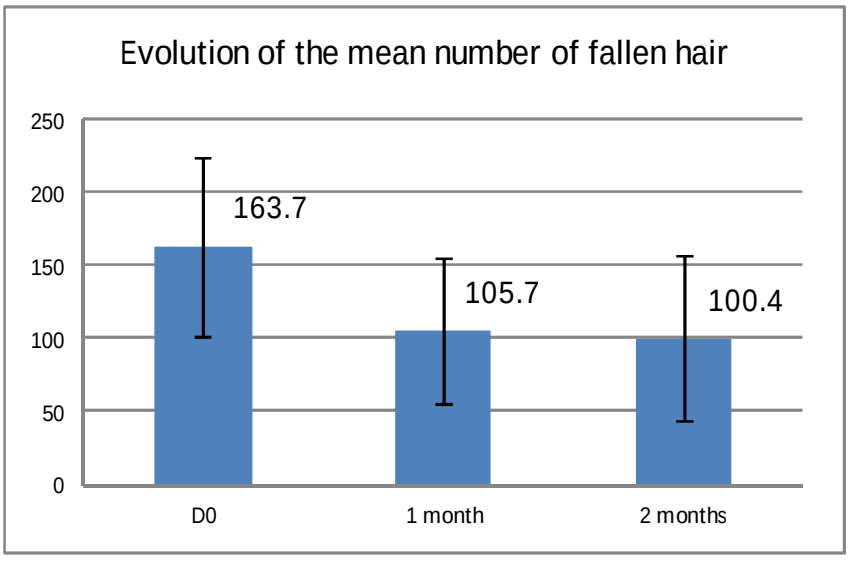
[1] permutations for paired data, ti vs t0 (i=1,2)

The numbers of lost hair **should decrease** with time when the treatment is active against hair loss.

Percentage of subjects showing a lower mean number of lost hair:

90% after 1 month of treatment (19 of 21)

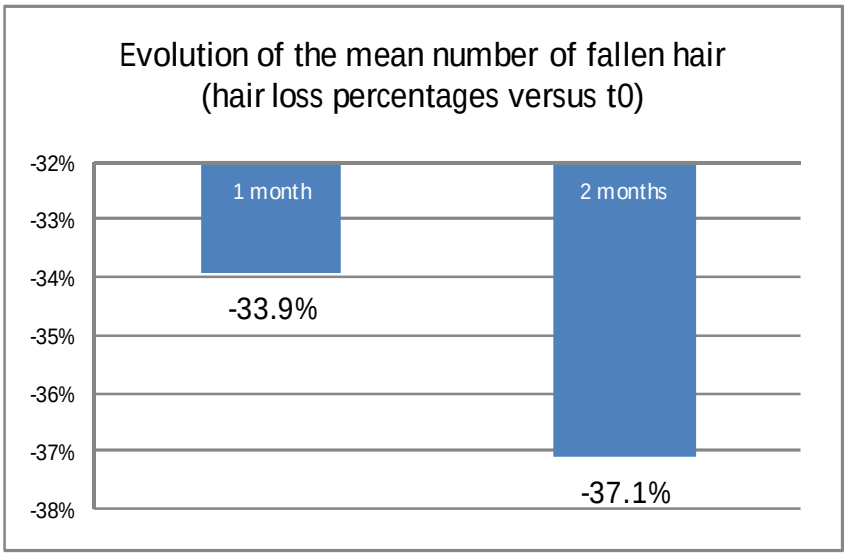
95% after 2 months of treatment (20 of 21)



Graph 1 – Graphical display of the mean number of fallen hair at each time point.

Statistical results (permutations):
t1 versus t0
p=0.0000 ***

t2 versus t0
p=0.0002 ***



Graph 2 – Graphical display of the relative percentage evolution of fallen hair at each time point versus t0.

The following comments can be made about the evolution of the number of daily fallen hair:

The mean hair fall results showed at each time point a statistically significant reduction of lost hair as follows:

- **After 1 month: -33.9%** (significant)
- **After 2 months: -37.1%** (significant)

- These hair loss percentages are very important. Both results at 1 month and 2 months are extremely significant. These results show that the test product has an important efficacy against hair loss.

- The evolution of hair loss percentages shows that more or less a maximum reduction has been reached already after 4 weeks of treatment, as only roughly 3% differ between -34% at t1 and -37% at t2.

2.3 Self-assessment questionnaire of product performance

Table 3 – Volunteers filled a questionnaire of product performance of the active product **P** at t2 (at the end of the treatment period, i.e. after 8 weeks of twice-daily applications). A 4-tiered rating scale was applied to each closed question, regarding volunteers' agreement with each of them (1=no, not at all, 2=no, 4=yes, 5=yes, absolutely).

Results are given in the following table 3:

Table 3 – Questionnaire results at t2. Total numbers of answers and corresponding percentages "agree" and "disagree".

Questionnaire of product performance after 8 weeks of treatment with S-577		agree			disagree	
Après 8 weeks of treatment…	Code	N	%	Signif.	N	%
…my hair is thicker.	Q1	9	43%		12	57%
…mes hair is stronger.	Q2	10	48%		11	52%
…I loose less hair daily.	Q3	18	86%	⇧	3	14%
…the overall condition of my hair has improved during the 8 weeks of treatment.	Q4	15	71%		6	29%
…I am satisfied from the performance of this product.	Q5	14	67%		7	33%
…I would like to continue following the treatment.	Q6	16	76%	⇧	5	24%
…I would like to purchase the product (regardless its price).	Q7	12	57%		9	43%
Statistical results are available upon request (binomial test with $p_0 = 0.5$, two-sided)						
Code = Question Nr.						
N = number of volunteers						
Signif. = significance						

The questionnaire results are detailed below:

Q1: **43%** of the volunteers consider that **their hair has become thicker** (9 of 21 answers, result is not significant);

Q2: **48%** of the volunteers consider that **their hair has become stronger** (10 of 21 answers, result is not significant);

Q3: **86%** of the volunteers **loose less hair daily** (18 of 21 answers, **significant result**);

Q4: **71%** of the volunteers consider that **the overall condition of their hair has improved during the 8 weeks of treatment.** (15 of 21 answers, result is not significant);

Q5: **67%** of the volunteers **are satisfied from the performance of this product** (14 of 21 answers, result is not significant);

Q6: **76%** of the volunteers **would like to continue performing the treatment** (16 of 21 answers, **significant result**);

Q7: **57%** of the volunteers **would like to purchase the product, regardless its price** (12 of 21 answers, result is not significant);

As a **conclusion**: the two assertions highlighted with green colour (Q3 and Q6, statistically significant) can be used for claim purposes.

3. CONCLUSIONS

Anti-hair loss performance
The results of this study demonstrate that the investigated food supplement **P**, coded (in this study) **S-577**, is effective as it significantly reduces the hair shedding rate.

The mean hair shedding results showed at each time point a statistically significant reduction of lost hair as follows:

- After 1 month: -33.9% (significant)
- After 2 months: -37.1% (significant)

- The evolution of hair loss percentages shows that more or less a maximum reduction has been reached already after 4 weeks of treatment, as only roughly 3% differ between -34% at t1 and -37% at t2.

Self-assessment questionnaires of product performance
After 2 months of regular once daily intake volunteers significantly appreciated the product **S-577** , regarding its overall performance on hair shedding. The following 2 assertions can be used for claim purposes:

Q3: **86% of the volunteers loose less hair daily** (18 of 21 answers, significant result);

Q6: **76% of the volunteers would like to continue performing the treatment** (16 of 21 answers, significant result);

This product was nicely tolerated by volunteers. No intolerance reaction was reported.

Considering these elements we recommend the food supplement coded (in this study) **S-577** as an effective treatment to reduce hair loss.

Neuchâtel, December 18, 2015

APPENDICES

Appendix 1 – Hair count results (EXCEL spreadsheets). These documents were sent electronically to the Sponsor.

Appendix 2 – Visioface photographs. These documents were sent electronically to the Sponsor.

Appendix 3 – Questionnaire results. This document was sent electronically to the Sponsor.

Appendix 4 – Study Protocol. See next page.

Appendix 3 – Study protocol

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Study protocol Nr. **P/1534_rev2.** Refers to the study offer Nr. O/15304_rev2 of September 4, 2015.

Client:	**Mibelle Biochemistry AG, Dr. Franziska Wandrey**
Title:	**Cosmetic efficacy study. Evaluation of the efficacy of a food supplement on hair loss (hair shedding).**
Objectives:	**Open, monocentric efficacy study (no placebo). In vivo evaluation of a hair shedding reduction. 2-month, intake of the food supplement; a visible and quantifiable hair shedding (hair loss) reduction is expected.**

Summary of the study plan:

Investigator:	Dr. Alain Béguin, Skin Test Institute (hereafter: STI)
Main objective:	Evaluation of the reduction of daily shedded hair: visible hair shedding reduction (photographs) and quantifiable hair shedding reduction (hair count)
Secondary objective:	Sensory evaluation. Consumer-oriented questionnaire at 2 months.
Type of study:	1 open, monocentric study on healthy male & female volunteers.
Duration of the study:	2 months, 3 meetings with volunteers (D0, D28, D56) and 9 hair collections.
Number of subjects:	20+2 volunteers (male & female).
Inclusion criteria:	- Male or female - Excessive hair shedding (more than 100 lost hair units daily) - Phototype I-III - Caucasian - Ages: 18-65 years - Healthy with no significant concurrent illness. - Having signed informed consent form after receiving the volunteer information and after the nature of the study has been fully explained.
Exclusion criteria:	- Non-matching scalp, resp. hair qualifications above - Incorrect ethnic origin - Phototype > III - Food allergy against legumes - Participation in any other clinical study/use of experimental drug(s) involving the test areas within the previous 8 weeks. - Use of any topical (drug containing) or cosmetic product on the test areas within 5 days before beginning the study. - Obvious medical pathologies such as AGA, Alopecia areata, Diffluvium - History or evidence of drug and/or alcohol abuse. - Severe systemic or dermatological disease. - Impaired cooperation possibilities or unwillingness to satisfactorily participate in the study. - Other(s), considered as important by the investigator
Products:	1 food supplement active ingredient against hair loss (hereafter **FS**, presented to volunteers as a water-soluble powder).
Treated/test areas:	Shedded hair (collected hair to be counted), overall head (photographs).

Product applications:

- Each volunteer receives **FS**, as an amount corresponding to the intake duration corresponding to 2 months.
- Volunteers take the product at home once daily, mornings. As the **FS** is a water-soluble powder, it is left free to volunteers to dissolve it in a cold liquid like water, fruit juice, etc.
- During the whole study volunteers apply a standard, neutral shampoo. Up to a certain point the choice of this product is left free to volunteers (this shampoo must not be specific, for example no anti-dandruff shampoo must be used).

Test parameters:

- Follow-up of the quantitative hair loss reduction, performed by counting lost hair collected by volunteers once daily (mornings, by combing hair) in envelopes.
- Follow-up of the visual hair loss reduction, performed by expert-grading evaluation of before/after photographs of the hairy area on top of the head. Device used: Visioface (Courage & Khazaka).
- Sensory evaluation questionnaire at 2 months.

Test procedure:

- ***D0-14 – D0-5 (2 weeks)***
  Recruitment phase
  Volunteers are recruited according to the inclusion and exclusion criteria given above. At this stage volunteers count their hair themselves. Reminder: inclusion condition is to loose an average number of 100 hairs per day (i.e. collected during the whole day).
- ***D0-4***
  First meeting with volunteers
  Volunteers sign the informed consent. Delivery of envelopes.
- ***D0-3 – D0-1 (3 days)***
  Baseline (hair collection, hair counting)
  Delivery of hair collection envelopes.Volunteers collect lost hair during 3 days (mornings, only combed hair) and place them in prepared envelopes (hair collections #1, #2, #3).
- ***D0***
  Meeting with volunteers
  Volunteers sign the informed consent. Volunteers deliver back the full envelopes #1, #2, #3.
  Delivery of **FS**, together with application instructions and application/ hair collection journal. Photographs. First hair count.
- ***D0-D27 (following 4 weeks)***
  1 product intake daily, mornings, by volunteers (drinkable solution in water).
- ***D25-27***
  Hair collections #4, #5, #6 (in envelopes), mornings (only combed hair).
- ***D28 (1 month)***
  Meeting with volunteers
  Volunteers deliver back the full envelopes #4, #5, #6.
  Photographs. Hair count (at STI).
- ***D29 – D55***
  1 product intake daily, mornings, by volunteers.
- ***D53-D55***
  Hair collections #7, #8, #9 (in envelopes), mornings (only combed hair).
- ***D56***
  Hair shedding evaluation
  Meeting with volunteers
  Volunteers deliver back the full envelopes #7, #8, #9.
  Photographs.
  Sensory evaluation questionnaire.

  End of the study.

Data evaluation:

Number of lost hair at the hair collection points. Photographs. Analysis of the sensory evaluation questionnaire: percentages of positive answers, graphical display.
Average calculations; a statistical evaluation on results will be performed as a non-parametric permutation analysis on paired data (Dx vs D0).

Study schedules:

- Weeks 34-40/15: recruitment of volunteers;
- Weeks 42-43: baseline hair collection by volunteers;
- Week 43: D0, 1st meeting with volunteers, 1st hair count;
- Weeks 43-46: 1st month of food supplement intake;
- Weeks 46-47: hair collection by volunteers after 1 month of supplementation;
- Week 47: D28, 2nd meeting with volunteers, 2nd hair count;
- Weeks 47-50: 2nd month of food supplement intake;
- Weeks 50-51: hair collection by volunteers after 2 months of supplementation;
- Week 51: D56, 3rd meeting with volunteers, 3rd hair count; sensory evaluation questionnaire;
- End of the study.

Results/Report delivery

Scheduled dates for results and report delivery are as follows:
- Test results in an electronic form are delivered to the Sponsor not earlier than 2 working weeks after the last skin measurement. Test results will be sent electronically on week 2, 2016, latest.
- Study report is first delivered to the Sponsor in electronic form, not earlier than 6 working weeks after the last skin measurement. Study report will be sent electronically on week 6, 2016, latest (pdf version). The paper version will be sent on week 7.

Confidentiality:

Absolute confidentiality about the nature and conditions of the project is ensured by the Skin Test Institute (regarding test results, volunteers' demography data and general project-related informations).

Signature

The undersigned Investigator of the study confirms that the present conditions are feasible and correspond to the purposed and expected assessments presented by the Sponsor upon study request. The present condition will be applied throughout the study, provided no unexpected issue takes place during the preparation or the progress of the study.

Neuchâtel, September 4th, 2015 (Dr. Alain Béguin)

Company: Mibelle biochemistry

1st Name/2nd Name: Franziska Waudrey

Function: Research and Study Manager

I agree with the present Study Protocol Nr. P/1534_rev2

(Date) 04.09.15

(Signature)