



Million(H)air®



Good Feeling
Hair Restorer Cream

Clinical trials / Efficacy & safety proofs



Dermatological test (PATCH TEST)

Evaluation of the potential irritant effect of a cosmetic product according to the amended Draize classification (on volunteers with sensitive skin).

Aim

To evaluate the tolerability of a cosmetic product through the individualization and the classification of its potential irritant potential.

Legal information

The evaluation of the possible irritating or sensitizing potential of the tested cosmetic products is a valuable aid to identify possible unwelcome effects in the use (REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.)

Study management and clinical trial services

- Technical report performed by BIO BASIC EUROPE s.r.l.
- Final technical report written by BIO BASIC EUROPE s.r.l.
- Experimentation performed at CDC - Dermo-clinic Research Institute

Execution of the test

- 25 volunteers with healthy sensitive skin and an age range of 18 - 70 years participated in the study
- The involved skin area (surface of the back) was cleaned with a 70% alcoholic solution
- The cosmetic product was applied in a quantity of 0.02 mg on ml/cm² of skin
- The involved skin area was occluded with the Finn Chamber (a plaster containing a 7 mm aluminium disk and disks of blotting paper)
- The cosmetic product was left in contact with the skin surface for 24 hours
- The Finn Chamber was removed
- The skin reactions were analysed 15 minutes, 1 hour and 24 hours after Finn Chamber removal.

Results

No skin irritations, erythema or edemas were observed.

Conclusion

This test can support the "dermatologically tested" and "not irritant" claims for the Million(H)air® Good Feeling Hair Restorer Cream.



Conclusions

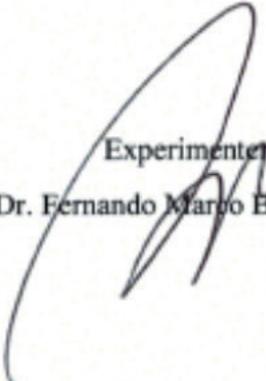
The table and the graphs listed above summarize the values of the indexes of erythema and edema found out for each volunteer. We can state that cosmetic product named:

Million(H)air Good Feeling Hair Restorer Cream

has been dermatologically tested and it can be classified according to amended Draize classification :

NOT IRRITANT

Experimenter
Dr. Fernando Mario BIANCHI



Quality Control
Dr. Claudio ANGELINETTA





Clinical study

Evaluation of the efficacy of a cosmetic product Million(H)air® in helping to prevent hair loss.

Aim

To evaluate the efficacy of the Hair Restorer Cream Million(H)air® in helping to reduce hair loss as well as its acceptability and scalp tolerability.

Study management and clinical trial services

- Technical report performed by BIO BASIC EUROPE s.r.l.
- Final technical report written by BIO BASIC EUROPE s.r.l.
- Experimentation performed at CDC - Dermo-clinic Research Institute

Execution of the test

- 20 volunteers, men and women, 10 with alopecia (baldness) and 10 with seasonal hair loss with an age between 29 and 60 years were selected for the study.
- Samples of the tested product were used for 84 consecutive days as follows: applied to dry head skin in the evening, allowed to take effect overnight and washed out in the morning.

The following parameters have been evaluated:

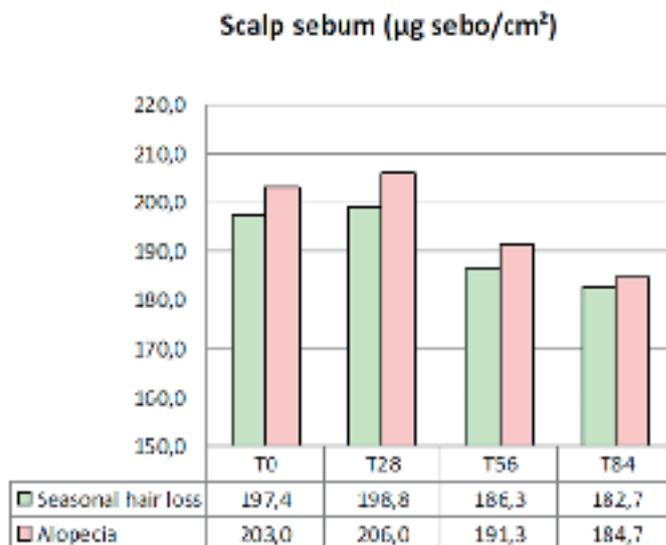
- Scalp sebum was measured with SEBUMETER® SM 815
- Phototrichogram to establish the % of hair for each of the 3 stages of the hair growth cycle (anagen, catagen, telogen)
- Index of hair fall based on the pull test and wash test indices
- Hair density was measured with microCAMERA® OT-2560 HAIR DENSITY OPTIC
- Onset of scalp reddening (as indication of scalp tolerability)
- Onset of scalp desquamation (as indication of scalp tolerability)
- Self-evaluation test of the volunteers according to Visual Numeric Scale (VNS) scale
- The statistical analysis was performed using Paired t-test and Wilcoxon rank sum test. Statistical significance was set at $P < 0.05$

Results

Scalp sebum statistically significant decreases of:

- 6% (seasonal hair loss and alopecia) after 56 days of product use
- 7% (seasonal hair loss) and 9% (alopecia) after 84 days of product use (Fig. 1)

Fig. 1. Effect of Million(H)air® on the sebum production of the scalp skin. After 56 and 84 days of product use statistically significant decrease of the scalp sebum was measured.



Activation of the hair growth (phototrichogram, alopecia).

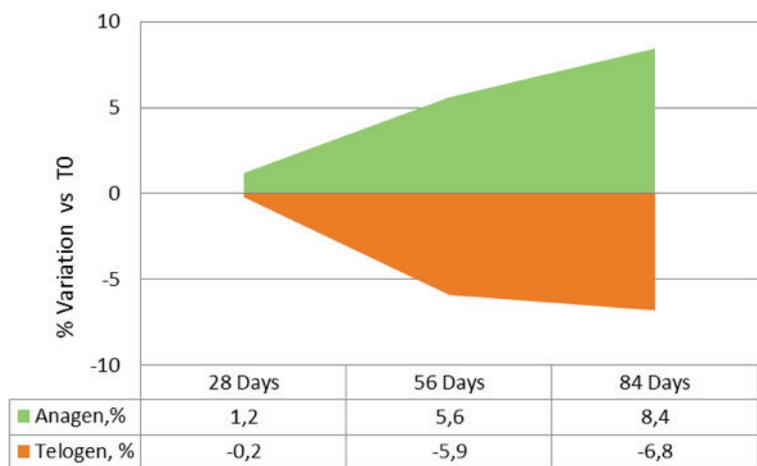
In people with healthy hair about 80-90% of hairs are in the anagen (active growth phase), 1-2% in the catagen, and 10-20% in the telogen (resting or hair loss) phases at any given time.

Values far different from these would indicate some health problem of hair, in particular if the percentage of anagen decreases whilst the percentage of telogen or catagen increases.

Clinical trial shows that Million(H)air® can

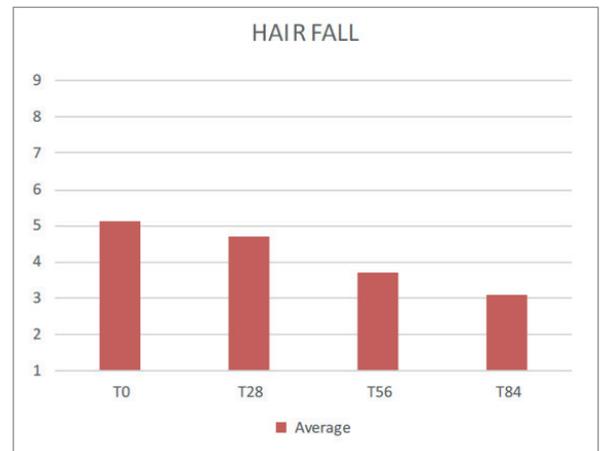
- increase the number of hairs in the active anagen phase by +8.4% after 84 days, at the same time
- decreasing the number of hairs resting in the telogen phase by 6.8% (Fig. 2).

Fig. 2. Average variations of hair in active (anagen) or resting (telogen) phases amongst volunteers with alopecia after using of Million(H)air®. Percentage variations are shown versus start time of the study (T0). Differences T0-T56 and T0-T84 are statistically significant (P<0.05).



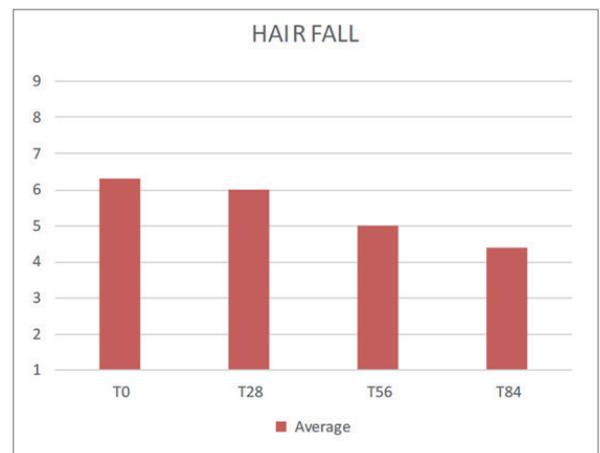
An Index of hair fall statistically significant improved in the 60% of the test persons with seasonal hair loss after 56 days of product use and in the 80% of the test persons after 84 days of product use (Fig. 3).

Fig. 3. Index of hair fall of the test persons with seasonal hair loss after using Million(H)air®. Differences T0-T56 and T0-T84 are statistically significant (P<0.05).



Amongst test persons with alopecia, index of hair fall improved in 50% of the panelists after 56 days of product use and in 70% of test persons after 84 days of product use (Fig. 4).

Fig. 4. Index of hair fall of the test persons with alopecia after using Million(H)air®. Differences T0-T56 and T0-T84 are statistically significant (P<0.05).



No scalp reddening or desquamation was recorded after 84 days of product use. Average hair density measured with microCAMERA® OT-2560 does not show a significant change after 84 days of product use, but a tendency towards improvement in hair density after using Million(H)air® is visible (Figs. 5, 6). It means also that Million(H)air® was able to prevent hair loss in volunteers.

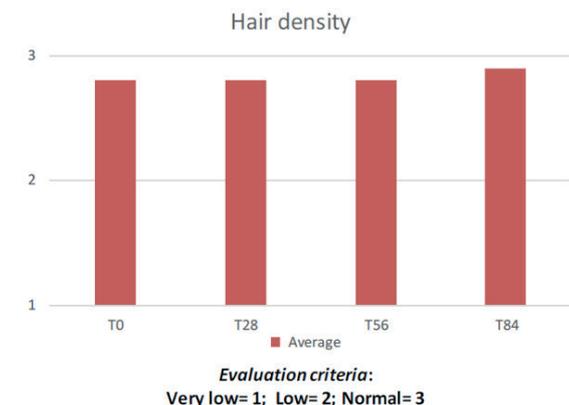


Fig. 5. Average hair density of the test persons with seasonal hair loss

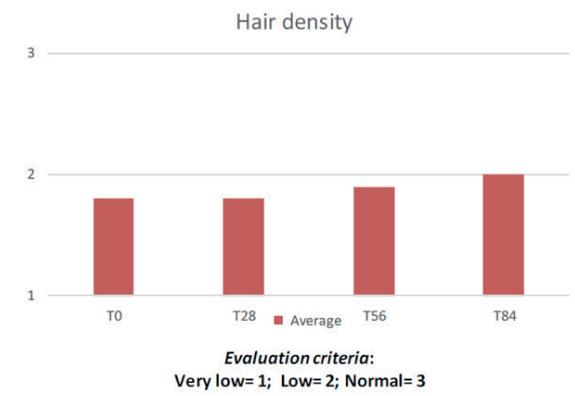


Fig. 6. Average hair density of test persons with alopecia

Some clinical photos and comments show an objective increase the hair density and the hair thickness.

Report no.1601111F

Good Feeling Products GmbH



Vol.02



T0

T84



T0

T84

Vol.0A



T0

T84

Vol.0B



From the analysis of the clinical photos of the first 3 test persons it is possible to observe at T0 time an initially notable and a diffused thinning in the fronto-parietal region, which expands until it reaches the top, associated with an attenuation of the shaft diameter, better appreciable along the center line.

At T84 time in all the 3 persons examined, it is clinically possible to objectively affirm a noticeable reduction of the thinning, with an increase of the density of the follicular units and a thickening of the hair shaft.

From the analysis of the clinical photos of the last two persons under evaluation it is possible to observe at T0 time a clinical situation typical of mild-moderate male androgenetic alopecia, affecting mainly the top of the head. Evident is a low density of the follicular units with a notable thinning of the shafts.

At T84 days in the 2 persons examined it is clinically possible to objectively affirm a noticeable reduction of the thinning, and an increase of the density of follicular units together with an improvement of the hair shaft thickness.



Conclusions

The clinical studies show, that Million(H)air®

- acts against seasonal hair loss and alopecia
- is effective in reducing the hair loss
- increases the number of hairs in the active anagen phase in cases of alopecia
- decreases the number of hairs resting in the telogen phase in cases of alopecia
- increases the density of follicular units (clinical observation)
- improves the hair thickness (clinical observation)
- reduces the hair fall rate
- normalizes the scalp skin, decreasing the sebum production
- is helpful for men and women
- provides good scalp tolerability
- has proven to be acceptable for volunteers

Hair Restorer Cream Million(H)air® is very well suited for men and women with problematic hair.

INGREDIENTS: AQUA (WATER), CETEARYL ALCOHOL, PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL, RICINUS COMMUNIS (CASTOR) SEED OIL, PENTYLENE GLYCOL, GLYCERIN, DICAPRYLYL ETHER, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, LECITHIN, SODIUM CETEARYL SULFATE, OLUS (VEGETABLE) OIL, MYRISTYL MYRISTATE, TOCOPHERYL ACETATE, FOMES FOMENTARIUS EXTRACT, POLYPORUS UMBELLATUS (MUSHROOM) EXTRACT, HYDROLYZED RICE PROTEIN, BIOTINOYL TRIPEPTIDE-1, RETINYL PALMITATE, MORINGA OLEIFERA LEAF EXTRACT, CAMELLIA SINENSIS (GREEN TEA) LEAF EXTRACT, PANTHENOL, CAFFEINE, BISABOLOL, EQUISETUM ARVENSE (HORSETAIL) EXTRACT, ALOE BARBADENSIS (ALOE VERA) LEAF JUICE POWDER, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, BENZYL NICOTINATE, ORYZANOL, XANTHAN GUM, SODIUM BENZOATE, POTASSIUM SORBATE, TOCOPHEROL, POTASSIUM HYDROXIDE, MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL, D-LIMONENE

Instruction for use

Apply the cream to the dry head skin and massage in lightly. Wash your hands thoroughly after application. Temporary redness of the head skin and pleasant feeling of warmth is possible and desired. Let the cream take effect overnight or for several hours. Then wash the cream out with shampoo and water if you find your hair to be too oily.

Warning

Not to be used for small children, on broken or irritated skin and on the mucous membranes in the eyes, mouth, nose or genital area. Otherwise wash immediately with water and soap. Keep out of the reach of small children.



CONCLUSIONS

According to the obtained results we can state that the cosmetic product:

Million(H)air Good Feeling Hair Restorer Cream

on the volunteers who underwent the test has proved to have a good scalp tolerability and efficacy in helping to reduce hair loss.
The product has also proved to have a sufficient acceptability.

Experimenter

Dr. Fernando Marco BIANCHI

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Quality Control

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