

Laboratory Test Report

Report Number: R-6519-238-11732

Page 1 of 1

Prepared for: Millionaire Smile Ltd

Address: Unit 17
The Matchworks
L19 2RF

Customer Sample Description: 170505 - MILLIONAIRE SMILE TEETH WHITENING STRIPS

Eurofins Registration Number: 6519 / 2019-753-2734

No. of samples: 1

Test(s) Performed: In-use test under dentist control during 2 weeks, efficacy whitening evaluation after the first application and after 2 weeks of use – dentist tolerance control performed before and after

Date Received: 16/08/2019

Date(s) Tested: 16/09/2019 – 23/10/2019

Results and Observations
Please refer to the following page(s)



Christine Dee
(Analytical Services Manager)

Date: 24/10/2019

The reported results relate exclusively to the tested sample.
The testing was performed by a laboratory within the Eurofins Group.

STUDY/PRODUCT REFERENCES: 19-1163/0 / 19.0522

**ASSESSMENT IN HUMAN OF THE TOOTH WHITENING EFFECT
OF A COSMETIC PRODUCT**

**CHECKING OF ITS ACCEPTABILITY AFTER APPLICATION
UNDER NORMAL CONDITIONS OF USE
SUBJECTIVE ASSESSMENT OF ITS COSMETIC QUALITIES
AND EFFICACY**

**-Use test with clinical control by an odontologist and with
objective evaluation-**

SPONSOR: MILLIONAIRE SMILE LTD

**TEST PRODUCT: MILLIONAIRE SMILE TEETH WHITENING
STRIPS**

Study report version 1

Barcelona, October 23rd, 2019

16 pages in this report including the Appendix

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I. AIM AND PRINCIPLE OF THE STUDY

This study intended to assess the **tooth whitening effect** as well as to check the **acceptability** and to assess the **cosmetic qualities and efficacy** of the product **MILLIONAIRE SMILE TEETH WHITENING STRIPS**, after application under the normal conditions of use planned by the Sponsor.

The **tooth whitening effect** of the product was assessed objectively and semi-quantitatively, by clinical score of the tooth colour shade following the R-20 Bleaching[®] Shade guide, performed by an odontologist before and after treatment.

The **acceptability** was:

- checked every day, by the subjects themselves at home,
- controlled after visual examination of the mouth, teeth and gums by an odontologist, and after questioning of the subjects.

The **cosmetic qualities and efficacy** were assessed, at the end of the study, using a target questionnaire.

II. TYPE OF THE STUDY

This monocentric study was performed in open.

The subject was used as own control.

It was performed according to the general conditions of Eurofins Cosmetics & Personal Care Spain, established for the performance of Human test project.

The test project was submitted to the previous agreement of the internal committee of Eurofins Cosmetics & Personal Care Spain before its performance (opinion n° CI-S38/19 of September 12th, 2019).

III. INVESTIGATOR CENTRE AND TECHNICAL STAFF

III.1. Investigator centre

EUROFINS PRODUCT TESTING, COSMETICS & PERSONAL CARE SPAIN, S.L.U.

Ausià March, 148-150
08013 Barcelona (Spain)

tel: (+34) 93.285.14.46

III.2. Technical staff

Investigator: Aracelly DEL PRADO (Odontologist)

Project Manager: Mireia LLOBET

Responsible technician: Guadalupe BRIONES

IV. DATES OF PERFORMANCE OF THE STUDY

Beginning on: September 16th, 2019

End on: September 30th, 2019

V. TEST PRODUCT

V.1. Identification of the test product

| | |
|--|---|
| Denomination | MILIONAIRE SMILE TEETH WHITENING STRIPS |
| Reference | |
| Batch number | 20190505 |
| Reference Eurofins | 19.0522 |
| Cosmetic form and organoleptic characteristics | Plastic strips |
| Number and type of samples | 728 strips / 26 boxes |
| Content of samples | 2 strips per box |

V.2. Information concerning the test product

The documents relating to the test product supplied with the samples were the qualitative and quantitative formula and the Sponsor's letter of agreement particularly concerning the conformity of the formula to the regulations in force and its safety.

VI. SUBJECTS

VI.1. Number

The number of subjects whose data had to be exploitable at the end of the study was 20, with a lower acceptable limit of 19, in accordance with the corresponding procedure.

22 subjects were included in the study.

1 withdrawal (subject ref. 16) was noted due to personal reasons not related with the study and no exclusion was decided by the investigator.

The acceptability, cosmetic qualities and efficacy and the tooth whitening efficacy of the test product were therefore assessed in 21 subjects.

VI.2. Specific inclusion criteria

The specific inclusion criteria were the following ones:

- age: 18-70 years old,
- sex: female and/or male,
- phototype (Fitzpatrick): I to V,

- having at least one natural teeth on central superior incisors (tooth 11 and 21) with colour shade at the inclusion $\geq S12$ and $\leq S30$, according to the following standard shade guide:



R-20 Bleaching® Shade guide

This guide has 20 shades that range from 2 to 40 and are arranged from lightest to darkest:

S2, S4, S6, S8, S10, S12, S14, S16, S18, S20, S22, S24, S26, S28, S30, S32, S34, S36, S38 and S40.

All the subjects corresponded to these specific inclusion criteria.

VI.3. Specific non inclusion criteria

The specific non inclusion criteria, defined in the protocol, were the following ones:

- personal history of adverse reactions to the same type of product as the one tested,
- presence of an odontological affection which could interfere with the interpretation of the results of the study,
- treatment with Vitamin A acid or its derivatives stopped less than 3 months before the beginning of the study,
- treatment with topical anti-inflammatory drugs on the mouth area stopped less than 8 days before the study,
- forecast of tooth care during the study,
- use of dental prosthesis or apparatus for the first time during the study,
- use of dental prosthesis affecting the central superior incisors, or forecast to use it for the first time during the study,
- presence of caries, dental abscess or untreated gum disease,
- with the evaluated central superior incisor (tooth 11 or 21) filled,

- whitening treatment less than 6 months before the study.

All the subjects corresponded to these specific non inclusion criteria.

VII. METHODOLOGY

The experimental conditions were the following ones:

| Experimental area | Product directions for use | Application at the investigator centre | Applications at home Frequency/duration |
|-------------------|---|--|--|
| Teeth | Apply the strips following the instructions of use below(*) | 1 st application on D0 | From D0 to D14 Application once a day for 14 +/- 1 consecutive day (2 weeks) |

(*)

1. Carefully tear open the pouch to reveal booth whitening strips
2. Start with the upper strip which is the longest one. Peel away the upper strip from the plastic backing and apply the gel side (the side touching the plastic backing) to the surface of your teeth.
3. Looking in a mirror, align the straight edge of the upper strip with your gumline and gently press it into place, making it completely stick to your teeth.
4. Apply the lower strip to your lower set of teeth in the same way.
5. After 60 minutes, remove the teeth whitening strips and discard of them safely in a bin.
6. Rinse your mouth with water and remove any excess gel that is still remaining with a clean tissue.

All the experimental conditions of application at the investigator centre were respected.

All the experimental conditions of use at home were respected by the subjects.

All the constraints of the study were respected by the subjects.

VII.1. Checking of the acceptability

The subjects were requested to note every day any reaction observed and sensation of discomfort felt on the **individual observation sheet** they were given at the beginning of the study.

A examination of the mouth, teeth and gums had to be performed by the odontologist.

This examination had to be performed visually under standard "daylight" source, before then after 14 +/- 1 consecutive days of use.

Concurrently with the clinical examination performed after use of the product, each subject had to be questioned about the possible sensations of discomfort he felt.

All the examinations were performed in accordance with the conditions defined in the protocol.

VII.2. Assessment of the tooth whitening effect

VII.2.1. Principle

The tooth whitening effect of the product was assessed objectively and semi-quantitatively, by clinical score of the tooth colour shade following the R-20 Bleaching® Shade guide (described in paragraph VI.2), before and after treatment.

VII.2.2. Score sites

The clinical score of the tooth colour was performed on one of the central superior incisors (tooth 11 or 21) by the odontologist.

VII.2.3. Subjects' position and room conditions

The subjects were reclined (approximately 45°) in supine position on a litter. The odontologist was placed in front of the subjects during the clinical score assessments.

The assessments were performed in a room without natural light in order to avoid interferences and under the artificial room illumination.

VII.2.4 Rate of the measurements

Clinical score was performed on **D0/T0**, just before the first application, on **D0/Timm**, immediately after the first application and on **D14**, at the end of the study.

VII.2.5. Expression and interpretation of the results

All the subjects included in the study were taken into account to assess the efficacy of the test product as long as they were submitted to all the examinations and measurements, at the defined times.

The individual results were expressed:

- in absolute values for each experimental time,
- in variations in comparison with D0/T0.

The means and standard deviations were calculated for all the experimental times.

The interpretation of the results was absolute, referring to **the results of the statistical analysis of the data** (comparison of the values obtained before and after treatment).

VII.3. Assessment of the cosmetic qualities and efficacy (self-assessment)

The subjects had to answer a questionnaire at the end of the study which gathered the items concerning the cosmetic qualities and efficacy of the product, defined with the Sponsor according to the category and target market of the test product.

For each item, the subjects had to express their satisfaction and the results were expressed in percentage of satisfied subjects.

VIII. RESULTS / DISCUSSION

Characteristics of the panel

| | | | |
|--|---|-------------------------------------|---------------------------------|
| Number of subjects included in the study | 22 | | |
| Withdrawal | 1 (ref. 16) for personal reasons not related with the study | | |
| Exclusion | None | | |
| Valid cases | Tooth whitening effect | Mouth, teeth and gums acceptability | Cosmetic qualities and efficacy |
| | 21 | 21 | 21 |

| Age (years) | Valid cases | |
|-------------|-------------|-----|
| Minimum age | 18 | |
| Maximum age | 70 | |
| Mean | 41 | |
| Criteria | Valid cases | |
| | Nb | % |
| Phototype | | |
| I | 0 | 0% |
| II | 6 | 29% |
| III | 10 | 48% |
| IV | 3 | 14% |
| V | 2 | 10% |
| Sex | | |
| Female | 14 | 67% |
| Male | 7 | 33% |

VIII.1. Checking of the acceptability

| Types of mouth and tooth reactions ascribable to the test product | % of subjects exhibiting clinical signs ascribable to the test product | Types of sensations of discomfort ascribable to the test product | % of subjects exhibiting sensations of discomfort ascribable to the test product |
|---|--|--|--|
| None | 0% | None | 0% |

Discussion:

Taking into account the sensations of discomfort felt by any subject and that any subject showed clinical signs ascribable to the test product, the odontologist classed the product in relation to the grading scale and judged it very well tolerated on the mouth area.

VIII.2 Assessment of the tooth whitening effect

1) Descriptive analysis

The tooth whitening effect of the product was assessed objectively and semi-quantitatively, by clinical score of the tooth colour shade following the R-20 Bleaching® Shade guide, performed by an odontologist before and after treatment.

The individual data (absolute values for each experimental time and its variation) are enclosed in **Appendix 1**.

The following table shows the mean values and standard deviations obtained for each experimental time and its variation (n=21 subjects).

| Tooth colour shade | | | | |
|--------------------|---------|--------|-----------------|-------------|
| Mean ± SD | | | Variation | |
| D0/T0 | D0/Timm | D14 | D0/Timm - D0/T0 | D14 - D0/T0 |
| 22 ± 6 | 20 ± 5 | 19 ± 6 | -2 | -3 |

Discussion:

Immediately after application, the tooth colour shade decreased a mean of 2 points. After 14 consecutive days of use, the tooth colour shade decreased a mean of 3 points.

2) Statistical analysis

The statistical analysis (Wilcoxon's signed exact rank test) allowed to compare the variation of the parameter before and after treatment.

| Wilcoxon's signed exact rank test | W value | p value | Significance of the difference* |
|-----------------------------------|---------|---------|---------------------------------|
| D0/Timm - D0/T0 | 136 | <0.0001 | S |
| D14 - D0/T0 | 210 | <0.0001 | S |

*S=significant if $p < 0.05$

NS=non significant

Conclusion:

The statistical analysis shows a statistically significant decrease of the tooth colour shade immediately after the first application, indicating that the product has an immediate tooth whitening effect. This decrease remained significant after 14 consecutive days of use.

VIII.3. Assessment of the cosmetic qualities and efficacy (self-assessment)

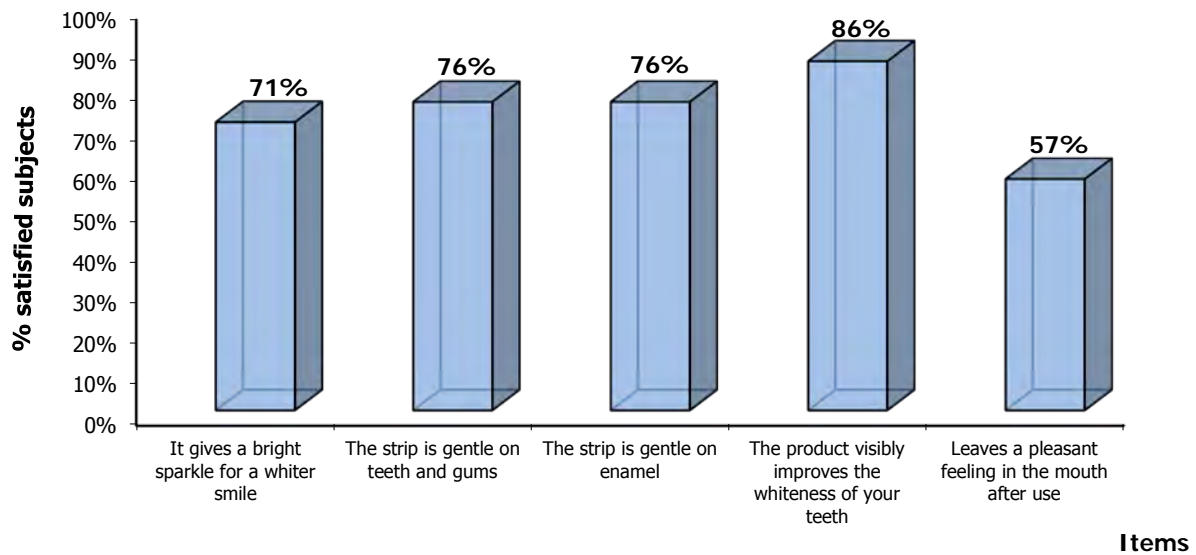
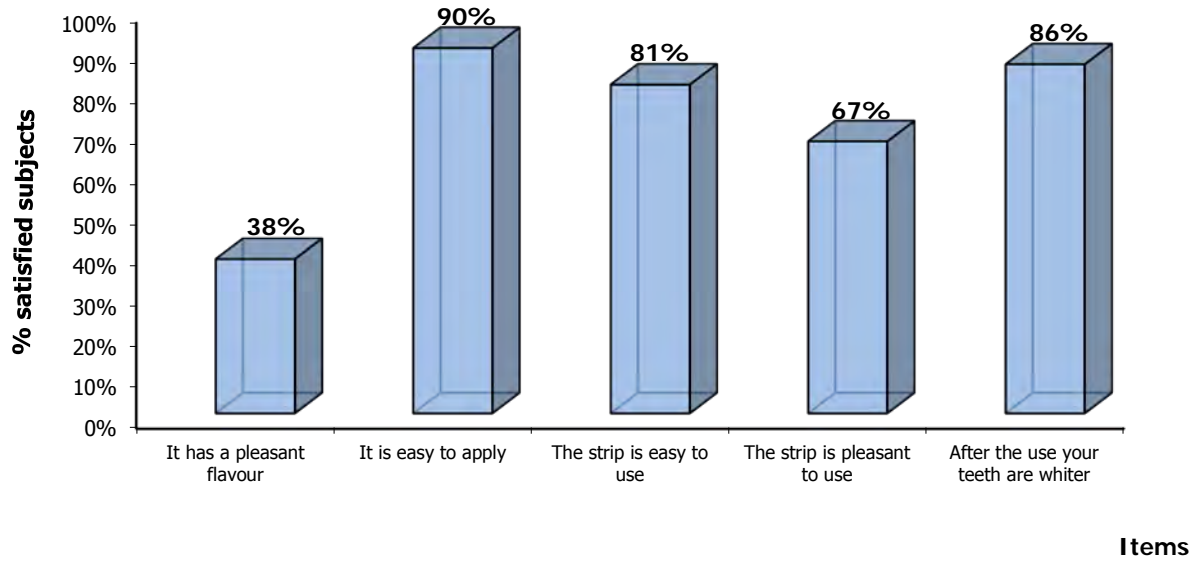
Global product evaluation

| I like it a lot | I quite like it | I like it a little | Neither like it nor dislike it | Not totally convinced | Don't like it very much | Don't like it at all |
|-----------------|-----------------|--------------------|--------------------------------|-----------------------|-------------------------|----------------------|
| 6 / 29% | 6 / 29% | 2 / 10% | 4 / 19% | 2 / 10% | 0 / 0% | 1 / 5% |

For each item, the number and percentage of subjects according to the score and the number and percentage of satisfied subjects is mentioned below:

| Item | N° and % of subjects | | | | N° and % of satisfied subjects |
|---|----------------------|----------------|-------------------|-------------------|--------------------------------|
| | Strongly agree | Slightly agree | Slightly disagree | Strongly disagree | |
| It has a pleasant flavour | 2 / 10% | 6 / 29% | 10 / 48% | 3 / 14% | 8 / 38% |
| It is easy to apply | 12 / 57% | 7 / 33% | 1 / 5% | 1 / 5% | 19 / 90% |
| The strip is easy to use | 13 / 62% | 4 / 19% | 3 / 14% | 1 / 5% | 17 / 81% |
| The strip is pleasant to use | 9 / 43% | 5 / 24% | 6 / 29% | 1 / 5% | 14 / 67% |
| After the use your teeth are whiter | 7 / 33% | 11 / 52% | 1 / 5% | 2 / 10% | 18 / 86% |
| It gives a bright sparkle for a whiter smile | 6 / 29% | 9 / 43% | 3 / 14% | 3 / 14% | 15 / 71% |
| The strip is gentle on teeth and gums | 13 / 62% | 3 / 14% | 5 / 24% | 0 / 0% | 16 / 76% |
| The strip is gentle on enamel | 9 / 43% | 7 / 33% | 4 / 19% | 1 / 5% | 16 / 76% |
| The product visibly improves the whiteness of your teeth | 6 / 29% | 12 / 57% | 0 / 0% | 3 / 14% | 18 / 86% |
| Leaves a pleasant feeling in the mouth after use | 4 / 19% | 8 / 38% | 4 / 19% | 5 / 24% | 12 / 57% |

For each item, the percentage of satisfied subjects is reported in the graphics below:



Purchase intention:

| Item | N° and % of subjects | | | |
|--|----------------------|---------------|------------------|--------------------|
| | Yes, definitely | Yes, probably | No, probably not | No, definitely not |
| If the price was adequate, would you buy this product? | 6 / 29% | 6 / 29% | 6 / 29% | 3 / 14% |

IX. CONCLUSION

According to the experimental conditions adopted and taking into account the grading scale established by the investigator centre, the product **MILLIONAIRE SMILE TEETH WHITENING STRIPS**

- has a very good acceptability.

Its very good mouth and teeth tolerance was thus confirmed.

The product can claim the mention "tested under control by an odontologist".

- has a statistically significant immediate tooth whitening effect, reducing a mean of 2 points the tooth colour shade, immediately after its application. After 14 consecutive days of use, this decrease remained significant, with a mean reduction of 3 points.

Signatures and dates

Investigator: Aracelly DEL PRADO (Odontologist)

I the undersigned, Aracelly DEL PRADO, declare that the overall conduct of the study was carried out under my responsibility and in the spirit of the Good Clinical Practices (International recommendations ICH topic E6, CPMP/ICH/135/95 of 1/5/1996, Directive of the European Parliament and Council 2001/20/EC – OJ/EC of 1/5/2001).



Project Manager: Mireia LLOBET

I the undersigned, Mireia LLOBET, declare that the content of the study report takes into account the recommendations of the Colipa relating to the assessment of the efficacy of cosmetic products (May 2008).



Quality Assurance Personnel: Marta RIVERA

I the undersigned, Marta RIVERA, declare that:

- this kind of study was audited according to the procedure of the investigator centre on September 16th, 2019,
- the report of the audit was transmitted to the Management of Eurofins Cosmetics & Personal Care Spain and to the Investigator,
- this final report was examined on October 23rd, 2019,
- the results reported accurately and completely reflect the raw data of the study.




 Eurofins Product Testing,
 Cosmetics & Personal Care Spain, S.L.U.
 NIF B-62074737

APPENDICES

Appendix 1

ASSESSMENT OF THE TOOTH WHITENING EFFECT
Tooth colour shade

| Subject's number | Tooth colour shade | | | | |
|------------------|--------------------|---------|-----|-------------|-----------|
| | Absolute values | | | Variation | |
| | D0/T0 | D0/Timm | D14 | DTimm-D0/T0 | D14-D0/T0 |
| 1 | 28 | 28 | 26 | 0 | -2 |
| 2 | 26 | 22 | 22 | -4 | -4 |
| 3 | 14 | 12 | 12 | -2 | -2 |
| 4 | 24 | 22 | 22 | -2 | -2 |
| 5 | 18 | 16 | 16 | -2 | -2 |
| 6 | 30 | 28 | 28 | -2 | -2 |
| 7 | 20 | 18 | 18 | -2 | -2 |
| 8 | 12 | 12 | 10 | 0 | -2 |
| 9 | 22 | 22 | 22 | 0 | 0 |
| 10 | 16 | 14 | 12 | -2 | -4 |
| 11 | 28 | 26 | 26 | -2 | -2 |
| 12 | 16 | 14 | 14 | -2 | -2 |
| 13 | 22 | 22 | 20 | 0 | -2 |
| 14 | 16 | 16 | 14 | 0 | -2 |
| 15 | 30 | 28 | 28 | -2 | -2 |
| 16 | WITHDRAWAL | | | | |
| 17 | 22 | 20 | 18 | -2 | -4 |
| 18 | 22 | 18 | 16 | -4 | -6 |
| 19 | 30 | 28 | 28 | -2 | -2 |
| 20 | 16 | 14 | 14 | -2 | -2 |
| 21 | 24 | 18 | 18 | -6 | -6 |
| 22 | 22 | 20 | 16 | -2 | -6 |
| Mean | 22 | 20 | 19 | -2 | -3 |
| Std. dev. | 6 | 5 | 6 | 1 | 2 |