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STUDY REPORT

These results concern only the samples tested in the laboratory which are defined here after.
The samples will be kept in our premises during 2 months from the date mentioned below.
The sample and the information regarding sample have been provided by the client. All information related to the sample are under liability of the client and have not been checked by the Eurofins ATS company.

EUROFINS BioPharma Product Testing Spain S.L.U.
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08028 BARCELONA

06/01/2015

ASSESSMENT OF THE EFFICACY OF A COSMETIC PRODUCT UNDER DENTIST CONTROL, AFTER A SINGLE APPLICATION, ON 20 ADULT VOLUNTEERS: Efficacy Test

Study sponsor: **Whitening World Ltd**

Study manager: **Elisa FAGGIANELLI**

Tested product:

- Name: Home Whitening Kit
- Product code: Home Whitening Kit BATCH 97409111
- ATS reference: 497361
- Brand: BEAMING WHITE
- Product type: Teeth whitening gel

Study n°: **220TUE20V14**

The copy of this report is only authorized by unabridged edition.
It is made of 19 pages.

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AUTHENTICITY OF THE STUDY REPORT

The study concerned by this report was carried out under my responsibility, according to the experimental protocol, the quality plan of EUROFINS ATS laboratory, and in accordance with the good clinical practices.
All observations and data taken during this study are reported in this report.

Study Manager, Elisa FAGGIANELLI

I certify the rereading of this report and I agree with its content,

Quality Assurance Reader, Elise ABRIC

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STUDY SUMMARY

ASSESSMENT OF THE EFFICACY OF A COSMETIC PRODUCT UNDER DENTIST CONTROL, AFTER A SINGLE APPLICATION, ON 20 ADULT VOLUNTEERS: Efficacy Test

- **Tested product:** Home Whitening Kit, referenced Home Whitening Kit BATCH 97409111

- **Study sponsor:** Whitening World Ltd

- **Objective:** The aim of the study is to assess the bleaching efficacy of the Home Whitening Kit product, after a single application, on 20 adult volunteers.

- **Investigator:** Frederic BIANCHI, Dentist, M.D.

- **Place of the study:** EUROFINS ATS, ACTIMART
  4 allée des Informaticiens
  1140 rue André Ampère
  13851 AIX EN PROVENCE cedex 3
  FRANCE

- **Study dates:** 04/12/2014

- **Method:**
  - ✓ ***Directions for use:***

The application was made at the laboratory by a technician.
Area of application: teeth using a tray
Quantity of product: 10ml of gel in total
The volunteer realizes a treatment consisting in 1 session.
Description of a session:

1- 1/3 of the gel is applied in the mouth tray (upper and lower arch). The frontal part- which is in contact with the front teeth- must contain enough product. If necessary some gel can be add on the empty spaces.
2- The tray is put in the mouth and the frontal part is pressed with the finger on the front teeth so that the gel is spread uniformly and that the 8 upper and the 8 lower teeth can be evenly covered.
3- Volunteers sit on a lightly reclined position.
4- The tray must be kept in the mouth during 35 minutes. After 35 minutes the tray is removed and thrown in the bin.
5- The mouth is rinsed with water.

✓ ***Assessment methods:***

The Dentist assessed the teeth's whiteness thanks to the R-20 Bleaching® Shade guide at the beginning (T0) and immediately after the session of 35 minutes (Timm).

✓ ***Panel:***

24 healthy adult volunteers (37,5% men and 62,5% women), non-users of tooth bleaching products, having yellow teeth, aged from 21 to 50 years old.
The assessment of the efficacy by clinical scoring was made on the 24 volunteers.

♦ **Results: Clinical scoring**

Immediately after the session, the teeth whiteness increased for the 24 volunteers (100%). The average bleaching efficacy is equivalent to a benefit of 3.6 shades.
These results allow highlighting a bleaching efficacy of the product immediately after the treatment.

♦ **Conclusion:**

To conclude, the single treatment of the Home Whitening Kit product, referenced Home Whitening Kit BATCH 97409111, on 24 healthy adult volunteers, non users of tooth bleaching product, having yellow teeth, aged from 21 to 50 years old, leads to a bleaching teeth improvement on 100% of the volunteers. The average bleaching efficacy is equivalent to a benefit of 3.6 shades.

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TABLE OF CONTENT

1 OBJECTIVE

The aim of the study is to assess the bleaching efficacy of the Home Whitening Kit product, on 20 healthy women and men, non-users of tooth bleaching products, having yellow teeth, aged from 18 to 50 years old.

2 METHODOLOGY

- ✓ Clinical observations are made by the Dentist at the beginning of the study to confirm the inclusion criteria and to examine the area that will be put in contact with the tested product.

- ✓ Assessment of the teeth's whiteness thanks to the R-20 Bleaching® Shade guide at the beginning of the study (T0).

- ✓ The product is applied by a technician at the laboratory, according to the conditions predefined with the study sponsor, 1 session of 35 minutes.

- ✓ Assessment of the teeth's whiteness thanks to the R-20 Bleaching® Shade guide after the session (Timm).

3 ETHIC AND REGULATORY CONSIDERATIONS CONCERNING PROTECTION OF PERSONS

3.1 Legislative and regulatory references

The French law relative to the Public Health n° 2004-806 of August 9, 2004 (articles 88 to 97) applied by the French Decree n° 2006-477 of April 26, 2006 for the research integrates the dispositions regarding the biomedical researches and replaces the French law of December 20, 1988 relative to the protection of persons who take part in biomedical researches called Law "Huriet-Serusclat". All tests carried out within EUROFINS ATS, even if they are not submitted to this law, are carried out according to this law.
The studies are carried out according to the most recent recommendations of the World Medical Association (Helsinki Declaration 1964, in its current version), and to the AFSSAPS recommendations relative to the biomedical researches on cosmetic products entering in the application field of the French law relative to the Public Health n° 2004-806 of August 9, 2004 (Version of September 7, 2006).
However, no information is sent to the national folder of people who takes part in biomedical research and the opinion of the "Committee of Persons Protection" is not asked.

The studies follow the *"Guidelines for the Evaluation of the Efficacy of cosmetic Products",* COLIPA, May 2008.

3.2 Ethic considerations

The ethic requirements, necessary to studies on Human, are respected:

- ✓ The volunteers are selected according to inclusion and non-inclusion criteria.
- ✓ All volunteers are informed of the aim and the type of the study, of the possible risks they are taken by participating in this study and give their free and informed consent before the beginning of the study.
- ✓ Before volunteers are exposed to the tested product, minimum information regarding the safety of the product is asked to the sponsor.
- ✓ All care is taken in order to avoid excessive oral or skin reactions or undesired effects on the volunteers' health during the study.
- ✓ Safety procedures are taken in case of bad reactions.
- ✓ The volunteers are paid in compensation for the time spent and the risks due to the study.

3.3 Confidentiality

The complete data regarding the health of the volunteers, collected during their final admittance in the volunteers database of EUROFINS ATS and necessary when recruiting and selecting them for the studies, are strictly confidential and submitted to the medical secret according to the article 378 of the "*Penal Code"* and to the article 4 of the "*Medical Ethics Code"* (R-4127-1 to R-4127-112 of the *"Public Health Code"* of December 14, 2006). The anonymity of the volunteers is respected within all studies carried out in our laboratories. However, each volunteer can be easily identified by the Investigator, the doctors and all the persons in charge of the study, thanks to its personal volunteer's code.
According to the article R. 5121-13 of the *"Public Health Code"*, the product type studied, the trials, the volunteers, and the results are strictly confidential and the secret is respected by the Doctors and all the persons working with them.
EUROFINS ATS ensures not to divulge all the data and results collected during a study.
Treatment of personal data is declared to CNIL.

3.4 Archiving

All data related to the study will be stored in the archives of EUROFINS ATS (Pôle d'activités d'Aix les Milles - ACTIMART – 4 allée des Informaticiens, 1140 rue André Ampère – 13851 AIX EN PROVENCE) and at a service provider's, Société Générale d'Archives (ZI Les Estroublans - 49 boulevard de l'Europe – 13127 VITROLLES), for 10 years.
At the end of this period, the study sponsor will have to specify whether the data related to the study should be thrown away or restored to him. Eurofins ATS can also consider extending the storage period of these documents, at the study sponsor's expenses.

4 QUALITY CONTROL AND INSURANCE

In order to meet client expectations and legal and regulatory requirements, EUROFINS ATS established all necessary resources for the management of its structural organizations and methods. With a constant client satisfaction policy, EUROFINS ATS chooses to follow the ISO 9001 requirements in order to establish the company organisation.

In this direction, this study was carried out in accordance with the procedures defined in the quality system. In order to insure results reliability, quality auto-controls are made all through the process.
Thus, during this study, all the documents, materials, environment and raw data were checked in order to avoid deviations from the protocol.

In the same way, under quality policy, the clinical tests laboratory is audited every year in order to assess that the procedures and instructions are well applied and to check their conformity with our internal requirements and process efficiency.

5 STUDIED PANEL

5.1 Number of volunteers

The product was tested by 24 volunteers. The test was carried out in open.

5.2 Recruitment, selection and final admittance of volunteers for a study

All volunteers recruited in this study come from the volunteers' data base of EUROFINS ATS, and answer the inclusion and non-inclusion criteria presented in the paragraphs below.
Their final admittance was determined by the study manager from the answers given in a pre-study questionnaire and after a preliminary interview. During this interview, the following information are explained to the volunteers: title, objective, protocol, planning of the study, payment methods, as well as the possible effects expected and the study constraints. The admittance of the volunteers is validated by the signature of the Information Note and a free and informed consent, by the investigator and the volunteers.

5.3 Inclusion criteria

The volunteers corresponding to the following criteria are included:

- ✓ Age : 18-50 years old,
- ✓ Gender: female or male,
- ✓ Non-users of tooth bleaching products,
- ✓ Presenting with yellow teeth,
- ✓ Social welfare: the volunteers must be affiliated at National insurance (French law : "Public Health Code" article L1121-11),
- ✓ No oral lesion on the studied area,
- ✓ Volunteers having a proof of home address,
- ✓ Volunteers able to understand French and the study requirements.

5.4 Non-inclusion criteria

- ✓ Volunteers not answering the previous inclusion criteria,
- ✓ Volunteers within an exclusion period between two tests,
- ✓ Minors or majors protected by the law and people admitted in a sanitary or social institution for other purpose than research (French law : "Public Health Code" article L1121-7),

- ✓ Persons deprive of liberty by legal or administrative decision, patients in emergency situation (French law : “Public Health Code” article L1121-6),
- ✓ Pregnant or breastfeed women (French law : “Public Health Code” article L1121-5)
- ✓ Volunteers presenting an evolutive oral pathology or a known contact allergy to one of the ingredients of the tested product,
- ✓ Volunteers who refused to give their free and informed consent,
- ✓ Volunteers under antihistaminic, corticoids, desensitizing treatment and/or under any treatment which could interfere with the oral metabolism.
- ✓ Volunteers with medicine stains such as tetracycline stains, fluorosis stains).

5.5 Banning and restrictions

For the whole length of the study, it is asked to volunteers not to take aspirin, anti-histamines, corticoids or anti-inflammatories that could interfere with the test results.

5.6 Volunteers withdrawal

Volunteers may be excluded from the study for the following reasons:

- ✓ They no longer follow the requirements and constraints of the study, explained during the signing of the consent,
- ✓ They suffer from an illness developed during the study which may interfere with the objectives of the study,
- ✓ They no longer wish to participate in the study.

6 TESTED PRODUCT

✓ Product name:	Home Whitening Kit
✓ Reference:	Home Whitening Kit BATCH 97409111
✓ ATS reference:	497361
✓ Presentation (galenic, colour):	White gel
✓ Packaging:	Syringe
✓ Number of samples received:	25
✓ Use by date:	< 30 months
✓ Storage conditions:	room temperature, away from light and heat.

A sample of the tested product is kept in EUROFINS ATS laboratory, during 2 months after the end of the study. After this date and except contrary order from the study sponsor, the product will be destroyed.

7 CLINICAL STUDY

7.1 Applying

The application was made at the laboratory by a technician.
Area of application: teeth using a tray
Quantity of product: 10ml of gel in total
The volunteer realizes a treatment consisting in 1 session.
Description of a session:

1- 1/3 of the gel is applied in the mouth tray (upper and lower arch). The frontal part- which is in contact with the front teeth- must contain enough product. If necessary some gel can be add on the empty spaces.
2- The tray is put in the mouth and the frontal part is pressed with the finger on the front teeth so that the gel is spread uniformly and that the 8 upper and the 8 lower teeth can be evenly covered.
3- Volunteers sit on a lightly reclined position.
4- The tray must be kept in the mouth during 35 minutes. After 35 minutes the tray is removed and thrown in the bin.
5- The mouth is rinsed with water.

7.2 Study protocol

2 weeks before D0:

✓ Selection of the volunteers from the data base, an appointment is taken.

D0:

✓ Welcoming of the volunteers, signature of the information and consent form, by the volunteers and the study manager. The volunteers also complete the medical auto questionnaire confirmed by the Investigator.
✓ Clinical exam at the beginning of the study: the Dentist examines individually the volunteers and assesses the mouth areas put in contact with the tested product.
✓ Teeth colour is scored by the Dentist using the R-20 Bleaching® Shade guide before treatment (T0).
✓ One session of 35 minutes is done according to the recommendations defined with the study sponsor.
✓ Teeth colour is scored by the Dentist using the R-20 Bleaching® Shade guide immediately after treatment (Timm).
✓ End of the study

7.3 Clinical assessments

The teeth colour is scored by the Dentist, using the R-20 Bleaching® Shade guide. This guide allows ranking the teeth whitening level for each volunteer at T0 and Timm.

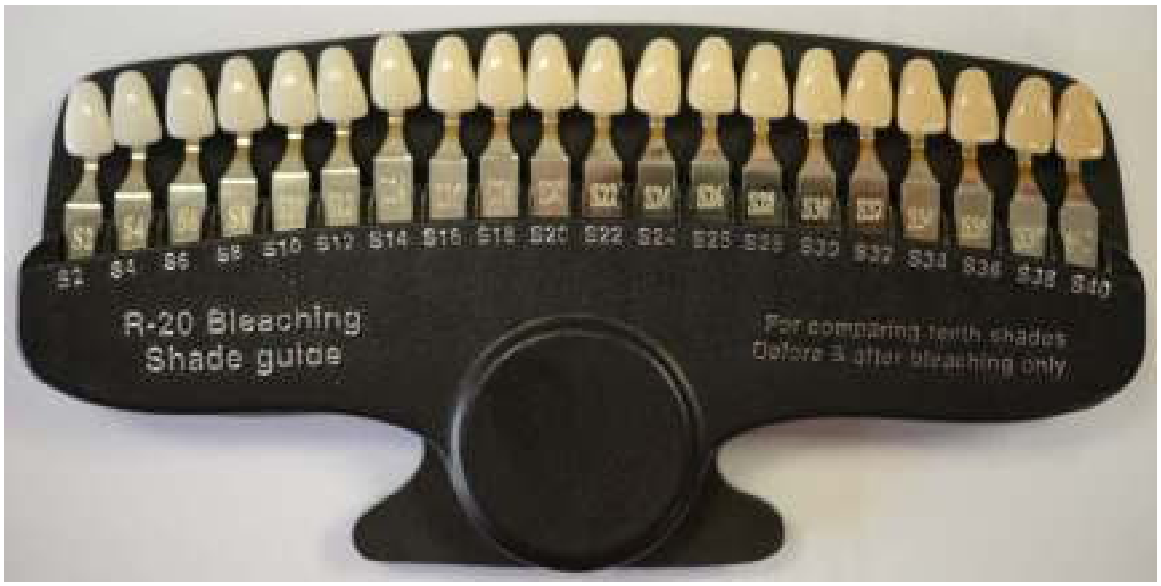

Figure 1: R-20 Bleaching® Shade guide

7.4 Data analysis and results interpretation

The results obtained are collected, analysed and interpreted by the study manager according to the effects expected.

The bleaching efficacy is determined by comparison of the scores Timm to T0. The conclusion regarding the product efficacy is given according to the average shades benefit and to the percentage of volunteers with an improvement.

8 RESULTS

8.1 Description of the panel

This study was carried out the 04/12/2014 and includes 24 healthy adult volunteers, whom characteristics are presented in *table 1:*

Table 1: Volunteers characteristics and events occurred during the study

VOL	VOL CODE	Gender	Age (years)	Yellow teeth	Non user of bleaching products
1	GALIS	F	45	Yes	Yes
2	VOLSY1	F	45	Yes	Yes
3	ARMMA	F	44	Yes	Yes
4	IOASA	F	41	Yes	Yes
5	MOUMA4	F	27	Yes	Yes
6	GAGEL	F	25	Yes	Yes
7	GARSA1	F	31	Yes	Yes
8	REBF2	F	23	Yes	Yes
9	JOIAL	M	48	Yes	Yes
10	CABSO1	F	25	Yes	Yes
11	BOUSA9	F	46	Yes	Yes
12	BACMA	F	46	Yes	Yes
13	BENDA2	M	46	Yes	Yes
14	JEARO	M	49	Yes	Yes
15	MARJE1	M	45	Yes	Yes
16	CHAJU	F	34	Yes	Yes
17	RIGBR	M	50	Yes	Yes
18	SAUMA	M	23	Yes	Yes
19	RUIJE	M	50	Yes	Yes
20	NGUOL	F	37	Yes	Yes
21	CALAL	M	47	Yes	Yes
22	PHICL	F	37	Yes	Yes
23	DANCE	F	21	Yes	Yes
24	CANCH1	M	48	Yes	Yes
Average			**39**		

None of the volunteers selected took a treatment contraindicated with the study.

8.2 Study exits

24 healthy adult volunteers (37,5% men and 62,5% women) aged from 21 to 50 years old were included in the study.
The product efficacy was evaluated on the 24 volunteers.

8.3 Results analysis

Immediately after the session, the teeth whiteness increased for the 24 volunteers (100%).
The average bleaching efficacy is equivalent to a benefit of 3.6 shades.
These results allow highlighting a bleaching efficacy of the product immediately after the treatment.

Appendix I presents the individual results of the clinical scoring by the Dentist.

9 CONCLUSION

To conclude, the single treatment of the Home Whitening Kit product, referenced Home Whitening Kit BATCH 97409111, on 24 healthy adult volunteers, non-users of tooth bleaching product, having yellow teeth, aged from 21 to 50 years old, leads to a bleaching teeth improvement on 100% of the volunteers. The average bleaching efficacy is equivalent to a benefit of 3.6 shades.

APPENDIX I

✓ ***Individual results of the clinical scoring by the Dentist***

APPENDIX I **Individual results of the clinical scoring by the Dentist**

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Product Home Whitening Kit **Study date** 04/12/2014
Reference Home Whitening Kit BATCH 97409111
ATS sample n° 497361

Study code 220TUE20V14

INCLUSION NUMBER	VOLUNTEER CODE	Whiteness at D0	Whiteness at D0Timm	D0Timm-D0
1	GALIS	22	12	-5
2	VOLSY1	12	6	-3
3	ARMMA	32	18	-7
4	IOASA	22	12	-5
5	MOUMA4	16	6	-5
6	GAGEL	12	6	-3
7	GARSA1	14	10	-2
8	REBF2	26	16	-5
9	JOIAL	18	12	-3
10	CABSO1	16	12	-2
11	BOUSA9	32	26	-3
12	BACMA	22	12	-5
13	BENDA2	12	8	-2
14	JEARO	32	26	-3
15	MARJE1	20	12	-4
16	CHAJU	14	8	-3
17	RIGBR	32	18	-7
18	SAUMA	24	20	-2
19	RUIJE	18	12	-3
20	NGUOL	14	10	-2
21	CALAL	28	24	-2
22	PHICL	22	14	-4
23	DANCE	14	10	-2
24	CANCH1	22	12	-5
Average				**-3,6**

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APPENDIX II

✓ ***List of the personnel who participated in the study***

Main investigator:
Name: Frederic BIANCHI, Dentist, M.D
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1140 rue André Ampère
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Study Manager:
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Laboratory technician, production assistant:
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Phone: 04 42 39 30 92

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APPENDIX III

✓ ***Results authenticity***

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AUTHENTICITE DES RESULTATS

RESULTS AUTHENTICITY

L'étude **220TUE20V14** a été conduite en conformité avec le protocole expérimental, le plan qualité du laboratoire EUROFINS ATS et dans le respect des bonnes pratiques cliniques.

The study **220TUE20V14** *was carried out in accordance with the experimental protocol, the quality plan of EUROFINS ATS laboratory and follows the good clinical practices.*

MEDECIN INVESTIGATEUR / *DOCTOR*
Dentiste / Dentist

Dr Fréderic BIANCHI

Date, signature

4/12/2014

TECHNICIEN / *TECHNICIAN*

COZZOLINO Stéphanie

Date, signature

04.12.2014