

PRELIMINARY STUDY REPORT

EUROFINS BioPharma Product
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21/11/2014

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: EU-COMPLIANT KIT
- Product code: EU-COMPLIANT KIT BATCH 97409052
- ATS reference: 490900
- Brand: BEAMING WHITE
- Product type: Teeth whitening gel

Study n°: 205TUE20V14

- ◆ **Tested product:** EU-COMPLIANT KIT, referenced EU-COMPLIANT KIT
BATCH 97409052
- ◆ **Study sponsor:** Whitening World Ltd
- ◆ **Objective:** The aim of the study is to assess the bleaching efficacy of the EU-COMPLIANT KIT product, after a single application, on 20 adult volunteers.
- ◆ **Investigator:** Frederic BIANCHI, Dentist, M.D.
- ◆ **Place of the study:** EUROFINS ATS, ACTIMART
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FRANCE
- ◆ **Study dates:** 06/11/2014

◆ **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 3 sessions.

Description of a session:

- 1- The bib is attached around the neck with the blue pin.
- 2- 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.
- 3- 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.
- 4- Volunteers sit on a lightly reclined position.
- 5- The volunteer wears protective glasses.
- 6- The LED Whitening Accelerator lamp is placed in front of the mouth (a distance of 5 cm between the lamp's head and the mouth is left) and then the START button can be pressed.
- 7- The tray must be kept in the mouth during 15 minutes. After 15 minutes the lamp is turned off. The tray can then be removed and thrown in the bin.
- 8- 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 3 sessions of 15 minutes (Timm).

✓ **Panel:**

20 healthy adult volunteers (30% men and 70% women), non-users of tooth bleaching products, having yellow teeth, aged from 19 to 50 years old.

The assessment of the efficacy by clinical scoring was made on the 20 volunteers.

◆ **Results: Clinical scoring**

Immediately after the 3 sessions, the teeth whiteness increased for the 20 volunteers (100%). The average bleaching efficacy is equivalent to a benefit of 3.5 shades.

These results allow highlighting a bleaching efficacy of the product immediately after the treatment.

◆ **Conclusion:**

To conclude, the single treatment of the EU-COMPLIANT KIT product, referenced EU-COMPLIANT KIT BATCH 97409052, on 20 healthy adult volunteers, having yellow teeth, aged from 19 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 3.5 shades.