Bionos

Testing Efficacy

USE TEST OF "*LAIT CORP FOR TATTOOS CARE REF. 1986.07 LOT 211125.007* "

Pharma&Beauty

FINAL REPORT - INF.1030.37.10

DATE – Feb. 9th 2022

Pharma&Beauty

USE TEST

Product:
"LAIT CORP FOR TATTOOS CARE REF. 1986.07 LOT 211125.007"

Ref. Report: INF.1030.37.10

RESEARCHER'S NAME	**DATE**
Adela Serrano Gimeno, PhD	09/02/2022

PROCEDURE'S DIRECTOR	**DATE**
José Luis Mullor Sanjosé, PhD	10/02/2022

DERMATOLOGICAL SURVEILLANCE	**DATE**
Dr. Miquel Armengot Carbó, PhD Dermatologist College Number: 4621665	10/02/2022

BIONOS BIOTECH
SCIENTIFIC DIRECTOR
José Luis Mullor Sanjosé, PhD jlmullor@bionos.es
PRINCIPAL RESEARCHER
Adela Serrano Gimeno, PhD aserrano@bionos.es
DERMATOLOGIST
Dr. Miquel Armengot Carbó, PhD. Dermatologist College Number: 4621665
COMPANY
Bionos Biotech, S.L. Avenida Fernando Abril Martorell 106, Tower A, 1st Floor 46026 Valencia (Spain) Phone: +96 124 32 19 bionos@bionos.es www.bionos.es

CLIENT
P&B Group Pharma & Beauty St Chamas en Provence, Z.A. Les Plaines du Sud 13250 Saint Chamas, France

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Executive Resume

GOAL

Clinical assessment of the topical treatment with "Use test of lait corp for tattoos care ref. 1986.07 lot 211125.007" (hereafter; Lait corp for tattoos care) on the tattooed area, during 21 days in 20 volunteers; through self-assessment questionnaire (use test) and dermatological surveillance.

METHODOLOGY

Twenty volunteers with sensitive skin were enrolled in treatment with "Lait corp for tattoos care" for 21 days on the tattooed area, twice per day (morning and evening). The volunteers filled in a self-assessment questionnaire (use test) at the end of the treatment (D21). Opinions were given according to parameters from 0 to 3. For positive impressions, satisfaction was considered when volunteers scored parameters from 2 to 3. Dermatological surveillance was included in the study.

RESULTS

The treatment was subjectively evaluated with a self-assessment questionnaire, showing an overall acceptance of 84% after 21 days of treatment with Lait corp for tattoos care. Specifically, positive evaluations (overall acceptance ≥ 80 %) were obtained for 4 out of 6 parameters regarding the cosmetic attributes, 10 out of 13 regarding the cosmetic effectiveness, and 3 out of 4 parameters regarding the consumer opinion.

Regarding skin compatibility and acceptability, none of the volunteers showed any skin acceptability problem, nor manifested any adverse symptom or cutaneous reaction during the treatment period or the days after.

CONCLUSION

The results from the self-assessment questionnaire after topical treatment with Lait corp for tattoos care indicated positive evaluations in general, with an overall acceptance average of 84% after 21 days.

Regarding dermatological surveillance, the product Lait corp for tattoos care showed good skin compatibility and may claim "Dermatologically tested", "Clinically Tested" and "Tolerance Tested".

1 Title

Use test of Lait Corp for tattoos care Ref. 1986.07 Lot 211125.007

2 Product tested

The tested samples were received in Bionos on 16/12/2021 at room temperature, and labeled as indicated:

Product: Lait Corp for tattoos care Ref. 1986.07 Lot 211125.007

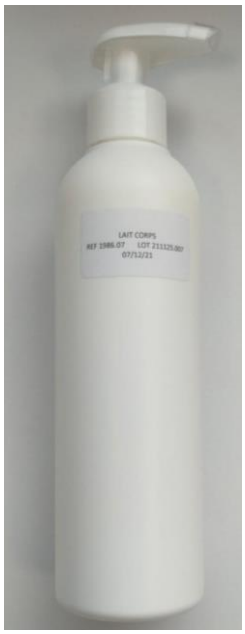

Figure 1: Lait Corp for tattoos care Ref. 1986.07 Lot 211125.007

The samples were stored at room temperature in our facilities and delivered to the volunteers before the start of the treatment.

3 Registration dates

- **Study begins**: 16/12/2021
- **Study ends:** 09/02/2022
- **Experimental phase begins:** 27/12/2021
- **Experimental phase ends:** 17/01/2022
- **Dates of measurements:** 1st 27/11/2021 – 2nd 17/01/2022

4 Platform

Twenty adult volunteers with sensitive skin

5 Material and Methods

5.1 Procedure

In this study, we assessed the effect of Lait Corp for tattoo care with a self-assessment questionnaire. For the self-assessment questionnaire, opinions are given according to parameters from 0 to 3, (0 = completely disagree / 1 = disagree / 2 = agree / 3 = completely agree). For positive impressions, satisfaction is considered when volunteers score parameters from 2 to 3. A significant percentage of volunteers is considered above 80 % (in this study n≥16 volunteers).

USE CONDITIONS

The product was self-applied by the volunteers twice a day (morning and evening) on the tattooed area.

PANEL

The panel represents the susceptible population to use the product. Inclusion criteria were:

- Adult Male and Female.
- In good general health (physical, mental, and social well-being, not merely the absence of disease/infirmity), according to subject self-report.
- Subjects with sensitive skin
- Understanding and signing a n Informed Consent (copy of original Informed Consent is shown in **Attachment 7).**

On the other hand, the exclusion criteria were:

- Nursing, pregnant, or planning to become pregnant individuals during the study according to the subject's self-report.

- In-use relevant pharmacological or hormonal treatment.
- Forecast for change of routine or relevant way of life, during the period of the study.

VOLUNTEERS

The number of volunteers according to the client's need was 20. Twenty-two volunteers were initially included in the study. Volunteer data is found in **Attachment 1.**

The self-assessment questionnaire was filled up by the 20 volunteers who completed the treatment. Raw data and additional comments from the volunteers are shown in **Attachment 5.**

STUDY OBLIGATIONS

Obligations imposed on volunteers were the following:

- To respect the conditions of use.
- Do not use other treatments on the tattooed area.
- To maintain those hygiene and cosmetics habits
- Do not include any new cosmetic or nutricosmetic product in their daily routine.

INFORMED CONSENT

Informed consent was obtained from each volunteer prior to initiating the study describing the study reasons, possible adverse effects, associated risks, and potential benefits of the treatment, as well as its limits of liability. The panelists signed and dated the informed consent document to indicate their authorization to proceed and acknowledge their understanding of the contents prior to the start of the study. The informed consent model is shown in **Attachment 7.**

IMAGE AND PERSONALITY RIGHTS

The sponsor (Pharma&Beauty) may use the pictures from all of the volunteers included in the study, for internal discussion of the results.

The sponsor (Pharma&Beauty) can make commercial and marketing use of the pictures from the volunteers who gave the consent to transfer their image and personality rights (for this specific study), according to the information shown in the table of **Attachment 1** (Volunteer data).

The sponsor (Pharma&Beauty) can make commercial and marketing use of the pictures from the volunteers who did NOT give the consent to transfer their image and personality rights (for this specific study), according to the information shown in the volunteer data table (**Attachment 1**), if they are able to assure the impossibility to recognize the person (e.g. using a black bar to completely cover the area of the eyes to avoid full personal recognition).

ETHICS

The study protocol is in accordance with the Scientific Committee on Consumer Safety (SCCS) guidance. It meets all international standards for research studies involving human subjects, the Good Clinical Practices (ICH-GCP), and World Medical Association. It has been conducted pursuant to the Declaration of Helsinki (1864), with the amendments of Tokyo (1975), Venice (1983), Hong Kong (1989), and Seoul (2008).

CHECKING OF THE ACCEPTABILITY

The subjects were requested to note daily any reaction observed, and sensation of discomfort felt. An examination of the experimental area under standard daylight source was performed by the responsible technician, the same days as the visits of start and end the assay

Together with the clinical examinations performed during the treatment, each subject was questioned by the responsible technician about the possible sensations of discomfort they felt, at the end of the study.

CONSUMPTION CONTROL

Consumption control was carried out to verify that volunteers followed the guidelines and applied the treatment. Product containers were weighed before and after the treatment. Data is shown in **Attachment 2**.

6 Efficacy Results

6.1.Self-Assessment questionnaire

The efficacy of the treatment was subjectively evaluated with test questions (self-assessment questionnaire), answered by each of the 20 volunteers, at the end of the treatment (D21).

For each attribute, the number and percentage of satisfied volunteers according to the punctuation are shown. For positive impressions, satisfaction was considered when volunteers either scored parameters from 2 to 3. Complete results for each volunteer are shown in **Attachment 4**

0 = Completely disagree
1 = Disagree
2 = Agree
3 = Completely agree

The results for self-assessment questionnaire are shown as follows:

COSMETIC EFFICACY	AVERAGE	0	1	2	3	% Satisfied
1. The application of the product is easy	**3**	0	0	3	17	**100**
2. The texture of the product is pleasant	**3**	0	0	6	14	**100**
3. Product absorption is fast	**2**	0	3	9	8	**85**
4. The perfume of the product is pleasant	**2**	3	2	9	6	75
5. The color of the product is nice	**3**	1	0	7	12	**95**
6. The product oils the skin	**1**	7	8	5	0	75
COSMETIC EFFECTIVENESS	**AVERAGE**	**0**	**1**	**2**	**3**	**% Satisfied**
7. My skin feels softer	**2**	1	1	13	5	**90**
8. My skin is less itchy	**2**	1	1	11	7	**90**
9. My skin is hydrated	**3**	0	0	8	12	**100**
10. My skin looks less irritated	**2**	1	1	12	6	**90**
11. My skin feels less strained	**2**	1	0	13	6	**95**
12. The tattoo color seems less faded	**2**	1	3	10	6	**80**
13. My skin is smoother	**2**	0	1	10	9	**95**
14. The tattoo seems more radiant/bright/contrasted	**2**	1	5	11	3	70
15. My skin seems more flexible (elastic)	**2**	1	3	13	3	**80**
16. I feel an immediate calming effect	**2**	3	5	10	2	60
17. My skin is more nourished	**2**	0	2	12	6	**90**
18. My skin feels comfortable all day	**2**	0	2	12	6	**90**
19. The treatment improves visually the quality of the tattoo	**2**	1	4	11	4	75
CONSUMER OPINION	**AVERAGE**	**0**	**1**	**2**	**3**	**% Satisfied**
20. I am satisfied with the treatment received	**2**	1	0	8	11	**95**
21. I would use the treatment again	**3**	1	1	3	15	**90**
22. I would recommend the treatment	**2**	1	1	8	10	**90**
23. I will buy the global treatment	**2**	1	5	10	4	70

A relevant percentage of volunteers (≥ 80 %) considered that:

- The application of the product is easy
- The texture of the product is pleasant
- Product absorption is fast
- The color of the product is nice
- Their skin feels softer
- Their skin is less itchy
- Their skin is hydrated
- Their skin looks less irritated
- Their skin feels less strained
- The tattoo color seems less faded
- Their skin is smoother
- Their skin seems more flexible (elastic)
- Their skin is more nourished
- Their skin feels comfortable all day
- I am satisfied with the treatment received
- They would use the treatment again
- They would recommend the treatment

The treatment was subjectively evaluated with a self-assessment questionnaire, showing an overall acceptance of 84% after 21 days of treatment with Lait corp for tattoos care. Specifically, positive evaluations (overall acceptance ≥ 80 %) were obtained for 4 out of 6 parameters regarding the cosmetic attributes, 10 out of 13 regarding the cosmetic effectiveness, and 3 out of 4 parameters regarding the consumer opinion.

7 Discussion and conclusions

In this study, we assessed the topical treatment with "Use test of lait corp for tattoos care ref. 1986.07 lot 211125.007" on the tattooed area, during 21 days in 20 volunteers; through a self-assessment questionnaire (use test) and dermatological surveillance.

For this, twenty volunteers with sensitive skin were enrolled in treatment with "Lait corp for tattoos care" for 21 days on the tattooed area, twice per day (morning and evening). The volunteers filled in a self-assessment questionnaire (use test) at the end of the treatment (D21). Opinions were given according to parameters from 0 to 3. For positive impressions, satisfaction was considered when volunteers scored parameters from 2 to 3. Dermatological surveillance was included in the study.

The treatment was subjectively evaluated with a self-assessment questionnaire, showing an overall acceptance of 84% after 21 days of treatment with Lait corp for tattoos care. Specifically, positive evaluations (overall acceptance ≥ 80 %) were obtained for 4 out of 6 parameters regarding the cosmetic attributes, 10 out of 13 regarding the cosmetic effectiveness, and 3 out of 4 parameters regarding the consumer opinion.

In regards to skin compatibility and acceptability, none of the volunteers showed any skin acceptability problem, nor manifested any adverse symptom or cutaneous reaction during the treatment period or the days after.

In conclusion, the results from the self-assessment questionnaire after topical treatment with Lait corp for tattoos care indicated positive evaluations in general, with an overall acceptance average of 84% after 21 days.

Regarding dermatological surveillance, the product Lait corp for tattoos care showed good skin compatibility and may claim "Dermatologically tested", "Clinically Tested" and "Tolerance Tested".

8 Registry and Regulation

The final report, the raw data and the assay protocol have been saved in digital format and on a paper copy. All the information provided by the client, volunteers and generated by Bionos Biotech will be considered *confidential*. The information about materials, reagents and protocols adopted by Bionos Biotech SL during the assays is confidential and will not be shared with third parties.

This study was performed under the principle of Good Clinical Practices (International Recommendations ICH Topic E6, CPMP/ICH/135/95 of May 1st 1996, European Parliament and Council Guideline 2001/20/CE – DOCE OF May 1st 2001).

Based on **Article 20 of Regulation (EC) No 1223/2009** on cosmetic products (CPR), **Commission Regulation (EU) No 655/2013** established EU harmonized common criteria in order to assess whether or not the use of a claim is justified.

Experimental studies include (but are not limited to) studies *in silico*, *in vitro*, *ex-vivo*, with instrumental or biochemical methods, studies conducted on volunteers, investigator evaluations, sensory evaluations, etc. Different types of experimental studies can be used to provide data on the performance of cosmetic products. Such studies should comprise methods that are reliable and reproducible. The studies should follow a well-designed and scientifically valid methodology according to best practices. The criteria used for the evaluation of product performance should be defined with accuracy and chosen in accordance with the aim of the test. The experimental aspect of studies calls for reliance on knowledge and awareness of statistical principles in the design and analysis of the study, e.g. in terms of number of subjects, test samples, etc. This is necessary in order to ensure that the studies achieve scientifically and statistically valid conclusions.

Studies conducted on volunteers should follow ethical principles and products tested should have been assessed as safe. Human studies should be conducted on the target population where necessary and be defined by strict inclusion/exclusion criteria.

Products may bear claims that relate to the nature of experimental studies. Consumer expectations regarding these claims may vary depending, in particular, upon the presentation of the claim and its specific context. However, in all circumstances, consumers will expect that such claims are made only when the effects tested are favorable:

- The claim "tolerance tested" means that the product underwent tests under the supervision of a scientifically qualified professional intended to study its tolerance on a target group and that the results of those tests show that the product was

well tolerated by this group.

- The claim "tested under medical supervision" indicates that the product underwent tests conducted under the supervision of a medically qualified professional, such as a medical doctor or a dentist. Depending on the presentation of the claim, it may, for example, refer to a specific efficacy of the product or to skin tolerance.
- The claim "dermatologically tested" implies that the product was tested on humans under the supervision of a dermatologist. Depending on the presentation of the claim, it may refer to a specific efficacy or tolerance of the product. Consumer self-perceptions studies are not appropriate to support such claims. The same logic would apply to a claim referring to any other medical discipline.
- The claim "clinically tested" refers to expertise, process or conditions under which the tests were carried out. "Clinically tested" means that the product was tested on humans under the supervision of a medically qualified professional or another scientifically qualified professional according to a clinical protocol or in a clinical setting.

The treatments tested in this **study 1030.37.10** may claim:

- **"Dermatologically tested".**
- "**Tolerance tested**".
- "**Clinically tested**".

A critical point for the validity of consumer tests is the wording of the questionnaire. The questions and proposed answers should be clear enough to be unequivocally understood by participants. The answers scale should be well balanced (e.g., the same number of positive and negative answers (a nominal, ordinal or visual analogical notation scale may be used)) and not capable of influencing the answer.

Special attention should be paid to the wording of questions for which responses will be used to substantiate the claim: the claim should be directly substantiated by the results related to the relevant question without any questionable interpretation.

Data processing and the interpretation of results should be fair and should not overstep the limits of the test's significance. Data recording, transformations, and representation in tabular or graphical form should be transparent or clearly explained if complex. It should not be designed to overstate the effect(s) measured. Appropriate statistical analysis of the data should be performed.

Attachments

Attachment 1: Volunteers data

Nº Volunteer	ID Volunteer	Age	Gender	Type of skin	Transfer of image and personality rights	Location of Tattoo
1	**1821**	31	Female	Sensitive	Yes	Right elbow
2	**507**	31	Female	Sensitive	Yes	Left forearm
3	**1952**	24	Male	Sensitive	Yes	Left forearm
4	**1401**	47	Female	Sensitive	Yes	Right arm
5	**2098**	33	Female	Sensitive	Yes	left forearm
6	**1778**	41	Male	Sensitive	Yes	Right arm
7	**2092**	33	Female	Sensitive	Yes	Right arm
8	**1603**	43	Female	Sensitive	Yes	Right thigh
9	**2080**	43	Male	Sensitive	Yes	Left arm
10	**1755**	20	Female	Sensitive	Yes	Left rib
11	**2060**	26	Male	Sensitive	Yes	Left arm
12	**944**	24	Female	Sensitive	Yes	Left arm
13	**2029**	22	Male	Sensitive	Yes	Left arm
14	**1336**	23	Female	Sensitive	Yes	Left rib
15	**1727**	48	Female	Sensitive	Yes	Right ankle
16	**600**	59	Female	Sensitive	Yes	Right arm
17	**1815**	30	Male	Sensitive	Yes	right leg
18	**1363**	40	Female	Sensitive	Yes	Left rib
19	**1985**	41	Female	Sensitive	Yes	Nape
20	**2099**	20	Female	Sensitive	Yes	Left arm

Attachment 2: Control consumption

VOLUNTEER	BASAL WEIGHT (g)	WEIGHT AFTER 21 DAYS (g)	PRODUCT USED AFTER 21 DAYS(g)
1	288,28	275,60	12,68
2	288,2	278,00	10,20
3	284,93	235,83	49,10
4	284,36	258,26	26,10
5	225,47	210,10	15,37
6	288,03	259,25	28,78
7	287,88	235,25	52,63
8	288,13	263,51	24,62
9	288,03	253,20	34,83
10	288,04	269,88	18,16
11	287,93	279,35	8,58
12	287,81	256,23	31,58
13	288,09	237,63	50,46
14	287,94	232,99	54,95
15	287,88	276,66	11,22
16	288,16	255,39	32,77
17	288,08	261,13	26,95
18	288,09	277,93	10,16
19	288,16	230,67	57,49
20	288,11	281,21	6,90

Attachment 3: Raw data from self-assessment questionnaires

QUESTIONNAIRE AFTER 21 DAYS																				
VOLUNTEERS	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
COSMETIC EFFICACY																				
1. The application of the product is easy	2	3	3	3	3	3	2	3	3	3	3	3	3	3	3	2	3	3	3	3
2. The texture of the product is pleasant	2	3	2	3	3	3	2	3	3	3	3	2	2	3	3	2	3	3	3	3
3. Product absorption is fast	3	3	2	2	3	3	1	3	1	3	2	3	2	2	3	2	2	2	2	1
4. The perfume of the product is pleasant	0	3	1	2	2	2	2	3	1	0	2	3	0	2	3	3	2	2	3	2
5. The color of the product is nice	0	3	2	2	3	3	2	3	3	2	2	3	3	2	3	3	2	3	3	3
6. The product oils the skin	0	0	2	1	1	2	0	1	0	0	1	0	2	2	1	2	1	0	1	1
COSMETIC EFFECTIVENESS																				
7. My skin feels softer	0	2	3	3	2	2	2	3	2	2	2	1	2	3	2	2	3	2	2	2
8. My skin is less itchy	0	2	2	2	2	2	3	3	3	3	2	1	3	3	2	2	2	2	3	2
9. My skin is hydrated	3	2	3	3	3	2	3	3	2	3	3	2	2	3	2	2	3	2	3	3
10. My skin looks less irritated	0	2	2	3	2	2	3	3	2	3	2	1	2	3	2	2	2	2	2	3
11. My skin feels less strained	0	2	3	3	3	2	2	3	2	3	2	2	2	2	2	2	2	2	2	3
12. The tattoo color seems less faded	0	2	3	2	2	3	2	3	2	1	1	1	3	2	2	2	3	2	3	2
13. My skin is smoother	3	2	2	3	3	2	2	3	2	3	3	1	2	3	2	2	3	2	2	3
14. The tattoo seems more radiant/bright/contrasted	0	2	2	2	1	2	2	3	1	2	1	1	3	3	2	1	2	2	2	2
15. My skin seems more flexible (elastic)	0	2	1	2	3	2	2	3	2	2	1	1	2	3	2	2	2	2	2	2
16. I feel an immediate calming effect	0	2	1	2	2	2	2	3	1	2	1	1	2	3	2	1	2	0	0	2
17. My skin is more nourished	3	2	2	3	3	2	2	3	1	2	2	1	2	3	2	2	2	2	2	3
18. My skin feels comfortable all day	3	2	1	3	2	2	2	3	2	3	2	1	2	3	2	2	2	2	2	3
19. The treatment improves visually the quality of the tattoo	0	2	2	2	2	2	2	3	2	2	1	1	3	3	2	2	3	1	2	1
CONSUMER OPINION																				
20. I am satisfied with the treatment received	0	2	2	3	3	2	3	3	2	3	2	2	3	2	3	2	3	3	3	3
21. I would use the treatment again	0	3	2	3	3	3	3	3	3	3	2	3	3	3	3	2	3	3	3	1
22. I would recommend the treatment	0	2	2	3	2	3	2	3	2	3	2	1	3	2	3	2	3	3	3	3
23. I will buy the global treatment	0	2	2	2	1	2	2	3	2	2	2	1	3	1	3	2	2	3	1	1

Attachment 4: Images

All images are enclosed in a digital file, together with this report, with the following folder structure:

1030.37.10 Photos

- **MACROSCOPIC PHOTOS**
  - V1
    - V1 D0 1030.tif
    - V1 D21 1030.tif

Attachment 5: Informed Consent

Nº VOLUNTARIO: ___

INFORMACIÓN Y AUTORIZACIÓN DE PARTICIPACIÓN EN EL ENSAYO	
Código de Protocolo: Pharma&Beauty ESTUDIO *IN VIVO* 1030.37.10	Promotor: Pharma&Beauty
Fecha de la versión: 16/12/2021	Investigador Principal: Dr Jose Luis Mullor SanJosé Dra. Adela Serrano Gimeno
CENTRO: BIONOS BIOTECH S.L.	

CONSENTIMIENTO INFORMADO:

Yo, _____

- He comprendido la información que se me ha facilitado.
- He podido hacer preguntas sobre el estudio.
- He recibido suficiente información sobre el estudio.
- Comprendo que mi participación es voluntaria.

He hablado con: Adela Serrano Gimeno

Apruebo la presente autorización. Firmado en Valencia ___/_____/ 21

COPIA PARA EL VOLUNTARIO

Biopolo La Fe | Hospital La Fe, Torre A, 1ª planta | 46026 Valencia (España)