ASSESSMENT OF AN SPECTRAL.LASH+ BY ANALYZING IMAGES FOR THE EFFECT ON EYELASH THICKNESS AND LENGTH (40245-01)

FINAL REPORT

TYPE OF PRODUCT: Eyelash pen
PRODUCT NAME SPECTRAL.LASH +
REFERENCE REGISTRATION: Allergisa Protocol APE_DS_LABORATORIES_RPRO_40245_V01

STUDY CODE: All-ES-40245-01-02-18
REPORT CODE: All-E-ES-AL-VOL-40245-01-02-18-Rev02

REPORT DATE: May 6, 2018

SPONSOR: DS LABORATORIES DO BRASIL
Rua Visconde de Inhaúma, 64, suite 404
20091-007 – Rio de Janeiro – Rio de Janeiro - Brazil
Telephone +55 (21) 9775-1484
Person responsible for study: Carlos Luzuriaga Castro

INVESTIGATOR: ALLERGISA PESQUISA DERMATO-COSMÉTICA LTDA
Av. Dr. Romeu Tórtima, 452/466 – Barão Geraldo
13084-791 – Campinas – SP – Brail
Telephone: +55 (19) 3789-8600

Investigator in Charge: Mariane Martins Mosca

ALLERGISA

ASSESSMENT OF AN SPECTRAL.LASHBY ANALYZING IMAGES OF THE EFFECT ON EYELASH THICKNESS AND LENGTH

ABSTRACT

Product Name: SPECTRAL.LASH +

Reference: Allergisa Protocol APE_DS_LABORATORIES_RPRO_40245_V01

STUDY CODE: All-ES-40245-01-02-18

Report Code: All-E-ES-AL-VOL-40245-01-02-18-Rev02

STUDY OBJECTIVE

The objective of this study was to assess eyelash thickness and length by Analyzing images taken 45 days following the use of the SPECTRAL.LASH product (40245-01).

METHODOLOGY

Two frontal pictures were taken of participant eyelashes using a Canon EOS Rebel T3i camera and the camera imaging software. Images were collected randomly. Images were acquired prior to applying the product and 45 days after using the SPECTRAL.LASH +. The product was applied twice daily, in the morning and in the evening for 45 (+/-) 2 days. The product was carefully applied to the upper eyelash, similar to how one would apply an eyeliner, and the procedure repeated on the lower lid.

INVESTIGATOR IN CHARGE

Mariane Martins Mosca.

DURATION OF TEST

45 days.

APPLICATION FREQUENCY

Twice daily.

AREA APPLIED

Upper and lower eyelid.

NUMBER OF PARTICIPANTS

SPECTRAL.LASH participants

DESCRIPTION OF THE POPULATION

Females between the ages of 23 and 64.

ETHICS

The study was performed according to the principles of the Helsinki Statement and all applicable regulations, including CNS Resolution n. 466/12, as well as Good Clinical Practice (Americas Document and ICH 6: Good Clinical Practice).

RESULTS/ CONCLUSION

Effects of the Product

Regarding the effect on **Eyelash Length**, the prodyct yielded a significant increase of 27.4% was found in Maximum and Mean Frontal Length after using the product for 45 days. The product yielded a significant increase of 20.1% in **Eyelash Thickness** after 45 days of use.

QUALITY ASSURANCE

This study complies with CNS Resolution n. 466/12, Good Clinical Practices and Allergisa Standard Operating Procedures.

The quality of the data is ensured, as our employees are trained and qualified for the research performed, our equipment is maintained and calibrated, and the methods used are known and/or validated.

The Quality Assurance Area monitors the research and welcomes clients who wish to specifically monitor the study, or to audit the Management System implemented.

Final reports are checked to ensure client satisfaction in terms of the services provided.

The signature of a Quality Assurance System representative means the study was conducted as described above, and that the results were checked against the source documents.

Quality Manager, Fátima
Ap. Ortigoza de Lima
May 6, 2018

CONTENTS

LIST OF ABBREVIATIONS

ANVISA	Brazilian National Health Surveillance Agency (ANVISA)
GCP/ICH	Good Clinical Practices/International Conference on Harmonization
CNS	Brazilian National Health Council
CIF	Clear and Informed Consent Form
T0	Initial time, before application of the test product
T45	Assessment time after 45 days applying the test product

9. Introduction:

The cosmetics industry has grown significantly in recent years, as has its interest in developing safe and effective products. The **Consumer Defense Code**, the demands of the Ministry of Health Surveillance Agency and the competition, have led industry players to be more cautious regarding the activity and benefits of their products, and most now attempt to associate product statements with scientific works.

Because of industry awareness and the demands of both consumers and the regulatory bodies, cosmetics manufacturers now use procedures that result in improved knowledge of their products. Before marketing a product, they conduct clinical safety and efficacy tests, coordinated by expert physicians. These procedures provide increased security and credibility, and increase consumer trust.

Research conducted on human beings is regulated and governed by rather strict legislation, designed to protect and safeguard individuals. These laws vary by country. This type of research is allowed in Brazil, so long as it follows the precepts of the Helsinki Declaration and CNS Resolution n. 466/12 (NATIONAL HEALTH COUNCIL, 2013)

This type of study enables assessing the sensory characteristics of the product, and detects additional comments and complaints regarding product performance.

To check if a [product] claim is valid one must consider overall consumer impressions of the product's presentation and/or advertising. [Product] Claims must be supported by solid, clear and relevant evidence. Such evidence may come from experimental studies (biochemical/instrumental methods, sensory, technical or photographic assessments, assessments that do not involve the research participants – in vitro studies using cell cultures, hair swatches, etc..) or from consumer assessments (ASTM E 1958-06).

The cosmetic product tested in this case was an SPECTRAL.LASH +.

2. Objective

The objective of this study was to assess eyelash thickness and length by analyzing images after 45 days of using the SPECTRAL.LASH +.

3. INVESTIGATIONAL PRODUCT

Product information as stated by the Sponsor is available in Attachment 5. A sample of the product was retained and cataloged and will be stored for one month.

3.1. Identification

Table 1. Information about the Test Product

Product:	INSTITUTE CODE	SAMPLE EXPIRATION DATE
SPECTRAL.LASH +	40245-01	August 5 2018

3.2. How to Apply the Product

Apply twice daily, in the morning and in the evening to a clean and make-up free face. Click on the button to dispense the solution. Carefully draw the applicator over the skin of the upper eyelid, as one would apply eyeliner. Repeat the procedure on the lower lid. For optimum hygiene, and to reduce the chance of eye infections, do not share your pen with others. Be very careful when applying the product to avoid injuring the eye. Suitable application requires that you place the tip close to the eye, thus a firm hand must be used when applying the product. Do not use this product if you cannot apply it safely.

3.3. Storage

The product provided by the sponsor was initially stored in the research center sample room, an access and climate-controlled environment. Product release was controlled by the principal investigator or by the technicians in charge assigned by the investigator.

4. APPLICABLE ETHICAL CONSIDERATIONS

This study was performed according to the principles of the Helsinki Declaration and applicable regulatory demands, including CNS Resolution n. 466/12, and in the spirit of Good Clinical Practice (Document of the Americas and ICH E6: Good Clinical Practice).

Participants were informed of the study objectives, methodology and duration, and of the potential benefits and restrictions associated with the study. Those who confirmed their interest in participating signed a Free and Informed Consent Form (Attachment 1).

The technical documentation related to the study will be kept on file at Allergisa for a period of 5 years.

5. STUDY PERIOD

The total duration of the study was 45 days.

- Starting date: February 26 2018
- Ending date: April 11 2018

6. Study participants

61.1. Recruiting Study Participants

Study participants were recruited by the Research Center recruiting Center, which keeps an updated computerized registration system (database). This database contains the names of people interested in

participating in studies. These were contacted to participate in the selection process. Those who met all of the criteria were included in the study.

6.2. Description of the Population

Twelve study participants were recruited for this study.
The study started out with 12 female participants between the ages of 31 and 64 (Attachment 4).

6.3. Inclusion Criteria

- Female;
- Aged between 18 and 65;
- Phototype I through VI;
- Intact skin in the test area;
- Healthy study participants;
- Agree to adhere to the study procedures and requirements, and come to the institute on the date and time stipulated for assessments.

6.4. Exclusion Criteria

- Pregnant or breast-feeding;
- Skin diseases in the area of product application;
- Type 1 diabetes mellitus;
- Gestational diabetes mellitus;
- Diabetes mellitus with complications (retinopathies, nephropathies, neuropathies);
- Insulin users;
- The existence of dermatoses related to diabetes mellitus (plantar ulcer, *necrobiosis lipoidica, granuloma annulare*, ermatophytosis, deep fungal infections, bacterial infections, opportunistic infections);
- A history of episodes of hypoglycemia, diabetic ketoacidosis and/or hyperosmolar coma;
- Immune deficiency;
- Use of systemic corticosteroids or immune suppressors;
- Skin diseases: vitiligo, psoriasis, lupus, atopic dermatitis;
- A history of reactions to the product category tested;
- Other diseases or medication that could directly interfere in the study or place at risk the health of the study participant.

7. Methodology:

The study was conducted according to Allergisa's operating procedures for performing tests on human beings and Allergisa Protocol APE_DS_LABORATORIES_RPRO_40245_V01.

7.1. Study Design

Open-label study.

7.2. Material and Equipment

- Canon EOS Rebel T3i camera and imaging software.
- Hair swatch;
- Software Image Pro® Plus.
- Canfield platform and support.

7.3. Study Area

The product was applied to the upper and lower eyelids of study participants.

7.1. Size of the Population

This study was conducted on 12 participants.

7.5. Image Acquisition

Before applying the product, images of the participant's faces were captured with the Canon EOS Rebel T3i camera and Canfield support to position faces. Two pictures were taken:
Frontal (left and right sides) to assess thickness and lengthening;
Participant faces were again photographed after applying the product for 45 days.
All study participants signed an image disclosure consent form. The identify of participants was preserved.

7.6. Image Analysis

Images were analyzed using Image Pro® Plus Software. The
following parameters were checked:
Eyelash Thickness: Measure of the total area occupied by the eyelashes in the image; Corresponds to volume.
Eyelash Length:

- Mean Frontal Length: Mean length of eyelashes as measured.
- Maximum Frontal Length: The length of the longest eyelash.

7.7. Schedule of Procedures

Table 2: Activities at each visit.

Steps	T0	T45
Signature of the Free and Informed Consent Form	X	
Signature of the Image Disclosure Form	X	
Image Capture (Canon EOS T3i)	X	X
Product and Mini-Diary Distribution	X	
Assessment of Adverse Events (if applicable)	X	X

7.8. Criteria and Procedure for Removing Subjects from the Study

The investigator could remove a participant from the study for any of the following reasons:

- Excluded study participants: those who signed the ICF but did not meet the study inclusion criteria;
- Participants who, in the opinion of the investigator, presented a problem that would impede the continued application of the product during the study period;
- Withdrawal of consent by the study participant, regardless of reason;
- Participant failure to adhere to the study. Failure of the participant to go to the center for assessments was considered significant failure to adhere to the study;
- Serious Adverse Event.
- Concomitant disease or treatment: any pathological process or treatment happening during the course of the study and capable of interfering with the study product, such as drug interactions, or of masking the results.

Participants removed from the study by the investigator were followed if they presented any event that may have been related to the study, even after their removal. Participants removed from the study due to adverse events were followed until the situation was completely resolved.

Participants removed following the study inclusion period were not replaced.

8. STATISTICAL ANALYSIS

An exploratory data analysis was performed (summary tables and charts). The two different times (T0 and T45) were compared using Student's t-test and a unilateral hypothesis for improvement. The number of study participants was 20.

The confidence level for comparative analyses was 95%. Software: used XLSTAT 2013 and MINITAB 14.

9. RESULTS

9.1. Adherence to Study

Twenty participants completed the study.
Participant 010 was excluded from the study as she chose to withdraw.
Participant 008 was excluded from the study due to an adverse event, as described below. On March 11 2018, the fourteenth day of the study, participant 008 came to the institute complaining of a burning sensation along the edge of the upper and lower eyelids of both eyes, followed by intense itching and local hyperemia immediately following the use of the test product. The participant reported feeling these effects since February 26, 2018, the first day of the study. Symptoms disappeared after the product was removed with chilled water.
The participant continued to use the product, and the complaints were repeated between the second and sixth day of the study, when she stopped using the product.
A clinical ophthalmic assessment was normal, with no clinical signs.
The participant was instructed not to use the product, to use compresses of chilled 0.9% saline and return on March 18 2018 for a new assessment.
On March 18 2018 the participant failed to come to the institute.
The participant was contacted by phone and a new visit was scheduled for March 25 2018. On March 25 2018, the participant came to the institute and had no complaints.
A clinical ophthalmic assessment was normal, with no clinical signs.
The test product was then applied at the institute under supervision. The participant reported mild stinging along the border of the lower eyelids immediately after application.
A clinical ophthalmic assessment performed immediately following supervised application was normal, with no clinical signs.
Considering that the symptoms returned following supervised application, the case was closed with a positive causal link. However, this adverse event was related to the participant's individual sensitivity and predisposition.

9.2. Results of the Effects Assessed

Data for participants 009 and 011 was excluded from the assessment of maximum frontal length. Data for participant 011 was excluded from the analysis of mean frontal length due to anomalies in the image analysis.

9.2.1. Mean Frontal Length

Table 3: Results observed, descriptive statistics and results (p-value) of the comparison between T45 and T0

Participant	T0	T45	Δ(T45 - T0)
1	339.6	427.9	88.3
2	568.8	750.8	182.0
3	351.7	432.6	80.9
4	542.8	743.6	200.8
5	378.5	499.6	121.1
6	459.9	593.3	133.4
7	360.8	497.9	137.1
9	468.4	562.1	93.7
11	342.8	414.8	72.0
12	362.1	488.8	126.7
13	346.4	446.8	100.5
14	580.2	696.2	116.0
15	358.7	466.4	107.6
16	553.7	692.1	138.4
17	386.1	513.5	127.4
18	469.1	605.1	136.0
19	368.0	496.8	128.8
20	477.8	482.0	4.2
21	349.7	486.0	136.4
Mean	424.47	541.91	117.44
Median	378.5	497.904	126.735
Minimum	339.6	414.788	4.232
Maximum	580.176	750.816	200.836
Standard Deviation	86.19	107.9	41.67
95% CI	[364.4; 483.0]	[379.7; 495.1]	[-12.5; 40.0]
	Δ (%) compared to T0		**27.4**
	% participants with increase		**100**
	p-value		**0.0007*** **

***significant at a level of 0.1%; ** significant at a level of 1%; * significant at a level of 5% (Student's t-test)

Compared to T0, the product promoted an increase in length of 27.4% with a 5% level of significance after 45 days of use.

9.2.2. Maximum Frontal Length

Table 4: Results observed, descriptive statistics and results (p-value) of the comparison at T45 and T0

Participant	T0	T45	Δ(T45 - T0)
1	417.9	551.628	133.728
2	747.8	1009.53	261.73
3	478.2	588.186	109.986
4	689.7	965.58	275.88
5	502.3	632.898	130.598
6	601.9	776.451	174.551
7	525.2	614.484	89.284
9	446.2	499.744	53.544
11	430.1	559.13	129.03
12	770.8	1002.04	231.24
13	492.9	606.267	113.367
14	710.3	894.978	184.678
15	517.8	704.208	186.408
16	619.3	792.704	173.404
17	541.0	714.12	173.12
18	459.2	583.184	123.984
19	532.1	649.162	117.062
20	425.8	476.896	51.096
21	370.2	499.77	129.57
Mean	**540.98**	**690.58**	**149.59**
Median	517.8	632.898	130.598
Minimum	370.2	476.896	51.096
Maximum	770.8	1009.53	275.88
Standard Deviation	117.9	171.5	61.52
95% CI	[467,9; 634,8]	[503,7; 651,2]	[-2,9; 55,2]
	Δ(%) compared to T0		**27.6**
	% participants with increase		**100**
	p-value		**0.0034*** **

***significant at a level of 0.1%; ** significant at a level of 1%; *** significant at a level of 5% (Student's t-test)

Compared to T0, the product promoted an increase in length of 27.6% with a 5% level of significance after 45 days of use.

9.2.3. Volume (Thickness)

Table 5: Results observed, descriptive statistics and results (p-value) of the comparison of results measured

Participant	T0	T45	Δ(T45 - T0)
1	114661	126273	11612
2	141307	180371	39064
3	117505	153505	36000
4	144921	191637	46716
5	63400	78819	15419
6	178674	179426	752
7	132813	155393	22580
9	108901	141301	32400
11	84521	90175	5654
12	121428	153781	32353
13	114663	126276	11613
14	141309	180374	39065
15	117507	153508	36001
16	144923	191640	46717
17	63402	78822	15420
18	178676	179429	753
19	132815	155396	22581
20	108903	141304	32401
21	84523	90178	5655
Mean	**120781.68**	**144610.95**	**23829.26**
Median	117507	153508	22581
Minimum	63400	78819	752
Maximum	178674	191640	46717
Standard Deviation	32141	37385	15269
95% CI	[100485; 141141]	[121386; 168750]	[14519; 33991]
	Δ(%) compared to T0		**20.1**
	% participants with increase		**100**
	p-value		**<0.001*** **

***significant at a level of 0.1%; ** significant at a level of 1%; *** significant at a level of 5% (Student's t-test)

Compared to T0, the product promoted an increase in volume with a 5% level of significance after 45 days of use.

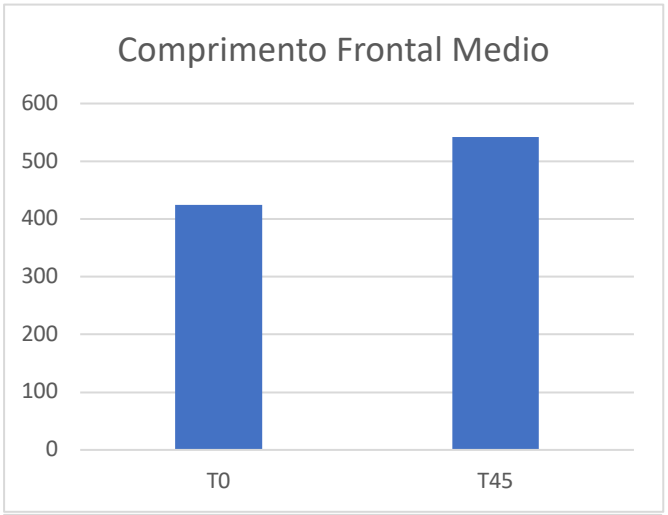
9.2.4. Summary of the Table

Table 7: Descriptive statistics of the difference between T45 and T0, results of the comparison and percent participants with increase and decrease.

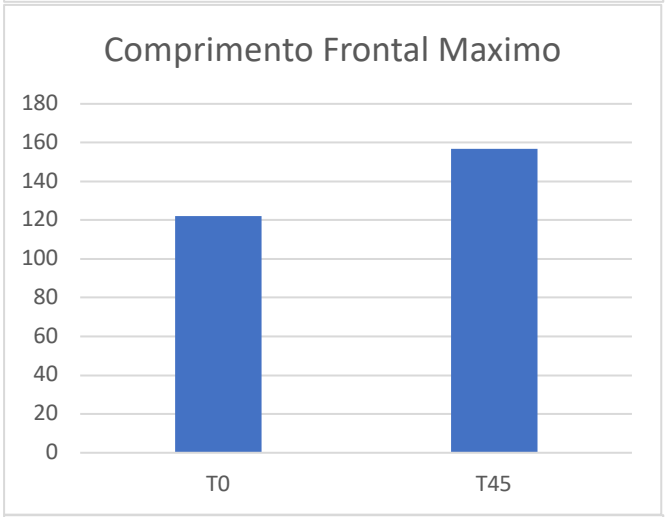
Parameter	Δ (%) compared to T0 (on average)	(T45 - T0) Mean ± Std. Deviation	Significant	Result	% participants with increase	% participants with decrease
Mean Frontal Length	27.4	86.19 ± 107.9	Yes (p<0.0007)	T45>T0	100	0.0
Maximum Frontal Length	27.6	117.9 ± 171.5	Yes (p<0.0034)	T45>T0	100	0.0
Volume	20.1	24255.0 ± 4868.0	Yes (p<0.001)	T45>T0	100.0	0.0

9.3. Charts

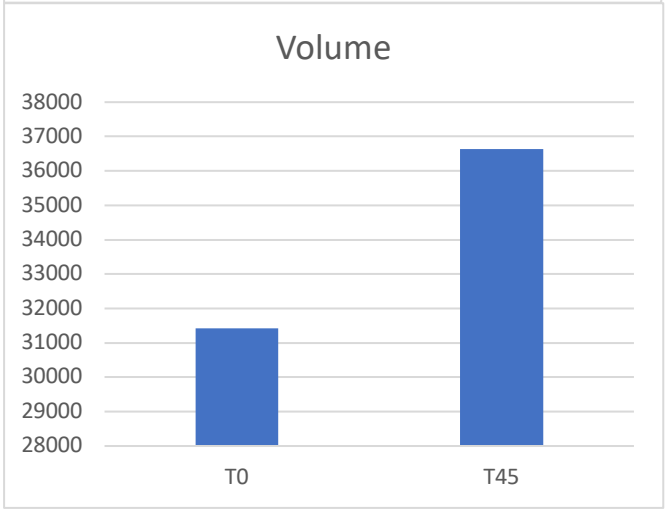
9.3.1. Comparison between T45 and T0



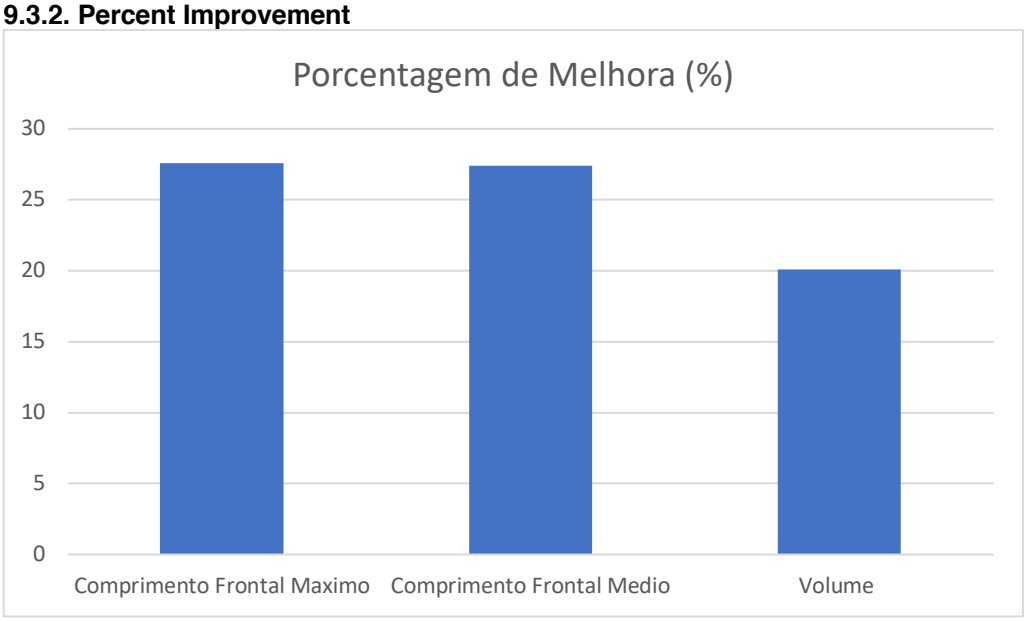
Mean Frontal Length



Maximum Frontal Length



9.3.2. Percent Improvement



Maximum Frontal Length Mean Frontal Length Volume

Y-axis Percent Improvement (%)

10. CONCLUSION

According to the methodology used to assess the effects of the product **SPECTRAL.LASH** submitted by **DS LABORATORIES DO BRASIL** on eyelash length and thickness, we find that:

Effects of the Product

- The product presented a significant increase in Eyelash Thickness. The mean percent improvement was 20.1. Eyelash thickness improved in 100% of the group participants after 45 days of use;
- The product presented a significant increase in Eyelash Length. The mean percent improvement was 27.6 Eyelash Length improved in 100% of the group participants after 45 days of use;

Technician in Charge
Mariane Martins Mosca
May 6, 2018

Principal Investigator
Vivian Pessoto Rosa
May 6, 2018

Statistician in Charge José
Marcos M. Vendraminni
May 6, 2018

11. REFERENCES

Brazilian National Health Council Health Ministry Resolution 466, Official Gazette (DOU) published on June 13, 2013.

INTERNATIONAL CONFERENCE FOR HARMONIZATION (ICH) Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance, 1996.

PANAMERICAN HEALTH ORGANIZATION. GOOD CLINICAL PRACTICE: Document of the Americas, 2005

Attachment 1 - Term of Free and Informed Consent

- You have been invited to participate in a study. We ask that you thoroughly understand all stages, and if you agree, sign this consent form;
- The objective of this study is to assess eyelash thickness and length by analyzing images after 45 days of continued use of the product.
- The study will be carried out at ALLERGISA Pesquisa Dermato-Cosmética Ltda., located at Av. Dr. Romeu Tórtima, 452/466 – Barão Geraldo – Campinas – SP;
- The study will be conducted on 12 participants;
- Your participation in the study will last for 45 (+/- 2) days.
- You will remain at the institute for about 4 hours.
- Front and side images of your eyelashes will be captured before you apply the product, and after you have used it for 45 days.
- Photographs will be taken with specific equipment. Taking pictures is fast and painless;
- You must comply with a number of requirements during the study period, and sign this Free and Informed Consent Form only if you agree to do so:
- **Do not apply any product to the experimental region that might interfere in the assessment of the study;**
- **Do not come in with makeup at T0 (the start of the study) or T45 (the end of the study);**
- You may be excused from the study after signing the free and informed consent form if you meet any of the study exclusion criteria, or if there are no longer any openings in the study;
- You state and warrant that you are not pregnant or breast-feeding, and agree not to become pregnant during the study period;
- Your consent does not exempt the organizers of the research center from their responsibilities;
- You are aware of the fact that, on occasion, a representative of the sponsor company may be present to observe the study;
- You agree that, within the context of the study, your data will be collected and may be subject to electronic processing. If any changes are made to your registration data (telephone number, address, etc...), please ask the study organizers to update it;
- There may be some discomfort and the appearance of signs or symptoms related to skin irritation, such as redness, scaling, itching or tingling. If you feel any of these symptoms please inform the study technician so that he/she may instruct you regarding the necessary procedures;
- As a benefit from participating in this study, you will contribute to launching a provenly safe and effective product for use on eyelashes.
- Any questions that arise during and after the study will be answered;
- Your participation in this study is totally voluntary.

- You will not be compensated for participating in this study, but will receive cash reimbursement in the amount of R$ 30,00 to cover expenses related to visits to the institute and the cost of transportation and meals;
- You may withdraw from the study at any time if you so wish, however you must inform the institute of your decision to withdraw.
- You may be removed from the study if you fail to fulfill your responsibilities according to the study protocol, or at the discretion of the investigator;
- Your voluntary collaboration will be of great importance to our work; therefore, we ask that you arrive on time on the dates stated over the course of the study;
- If there is any change to your habits, we ask that you please tell us for better interpretation of the results;
- Do not use any type of product (e.g.: deodorant or antiperspirant, talcum powder, bath oils, creams, lotions, perfumes, colognes, or topical medications) on the areas adjacent to the test area. If you use any of these products or take systemic medication, please let us know;
- Should you feel persistent moderate or intense itching or any other signs of irritation inform the center immediately, either by coming to the test application area or by phone 19-3517-6800 (during regular business hours) or 19-9778-0204 (between 8:00 am and 10:00 pm);
- We guarantee that any adverse reaction caused by the test product will be monitored by the dermatologist in charge of the project is completed, and that suitable medication will be provided if necessary;
- Potential indemnification is assured;
- We guarantee that any new relevant information that could interfere in your consent will be communicated;
- All raw materials used in the product are approved for topical use and are non-toxic. However, like any product, it may cause unexpected reactions such as “redness”, “swelling”, “itching” and “burning” in the areas where the product is applied;
- All of the data about the participants shall be kept confidential. However, in signing this form you are allowing the sponsor and regulatory authorities to audit all study documents and data;
- If you have any questions or problems, you may contact the medical team, through Dr. André Luiz Vergnanini, Principal Investigator, by phone at 19 3789-8615.
- One copy of this form will remain on file with Allergisa and the other will be given to the study participant.

I agree to participate in the study "**ASSESSMENT OF EYELASH THICKNESS AND LENGTH"** and state that all of the items above have been explained to me.

Volunteer's Signature (as it appears on the id (R.G.) or Driver's License C.N.H.)

Date

Signature of the Person Responsible for applying the ICF

Date

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Attachment 2 - Statistical analysis

Results for: CFme

Descriptive Statistics: T0; T45

	T0	T45	Δ(T45 - T0)
Number of values	19	19	19
Minimum	339.6	414.8	4.2
25% Percentile	351.7	466.4	93.7
Median	378.5	497.9	126.7
75% Percentile	477.8	605.1	136.4
Maximum	580.2	750.8	200.8
Range	240.6	336	196.6
5% Percentile	339.6	414.8	4.2
95% Percentile	580.2	750.8	200.8
95% CI of median			
Actual confidence level	98.08%	98.08%	98.08%
Lower confidence limit	351.7	466.4	93.7
Upper confidence limit	477.8	605.1	136.4
Mean	424.5	541.9	117.4
Std. Deviation	86.19	107.9	41.67
Std. Error of Mean	19.77	24.76	9.559
Lower 95% CI of mean	382.9	489.9	97.35
Upper 95% CI of mean	466	593.9	137.5
Coefficient of variation	20.30%	19.92%	35.48%
Geometric mean	416.7	532.5	100.5
Geometric SD factor	1.215	1.208	2.246
Lower 95% CI of geo. mean	379.5	486.1	68.03
Upper 95% CI of geo. mean	457.7	583.3	148.4
Harmonic mean	409.6	523.9	48.33
Lower 95% CI of harm. mean	376.3	482.5	0
Upper 95% CI of harm. mean	449.3	573.1	21.7
Quadratic mean	432.7	552	124.2
Lower 95% CI of quad. mean	386.8	493.7	104.7
Upper 95% CI of quad. mean	474.2	604.7	141.1
Skewness	0.7187	0.8805	-0.646
Kurtosis	-1.078	-0.4923	2.554
Sum	8065	10296	2231

Results for: CFMa

Descriptive Statistics: T0; T45

	T0	T45	Δ(T45 - T0)
Number of values	19	19	19
Minimum	370.2	476.9	51.1
25% Percentile	446.2	559.1	113.4
Median	517.8	632.9	130.6
75% Percentile	619.3	792.7	184.7
Maximum	770.8	1010	275.9
Range	400.6	532.6	224.8
5% Percentile	370.2	476.9	51.1
95% Percentile	770.8	1010	275.9
95% CI of median			
Actual confidence level	98.08%	98.08%	98.08%
Lower confidence limit	446.2	559.1	113.4
Upper confidence limit	619.3	792.7	184.7
Mean	541	690.6	149.6
Std. Deviation	117.9	171.5	61.52
Std. Error of Mean	27.06	39.36	14.11
Lower 95% CI of mean	484.1	607.9	119.9
Upper 95% CI of mean	597.8	773.3	179.2
Coefficient of variation	21.80%	24.84%	41.12%
Geometric mean	529.5	671.8	136.9
Geometric SD factor	1.235	1.269	1.574
Lower 95% CI of geo. mean	478.3	599	110
Upper 95% CI of geo. mean	586.1	753.5	170.3
Harmonic mean	518.7	654.6	123.1
Lower 95% CI of harm. mean	472.4	590.3	97.86
Upper 95% CI of harm. mean	575.2	734.8	165.7
Quadratic mean	553	710.5	161.1
Lower 95% CI of quad. mean	489.8	616.8	126.7
Upper 95% CI of quad. mean	609.7	793.2	189.4
Skewness	0.6912	0.7563	0.4946
Kurtosis	-0.55	-0.6038	0.003779
Sum	10279	13121	2842

Results for: Volume

Descriptive Statistics: T0; T45

	T0	T45	Δ(T45 – T0)
Number of values	19	19	19
Minimum	63400	78819	752
25% Percentile	108901	126273	11612
Median	117507	153508	22581
75% Percentile	141309	179429	36001
Maximum	178676	191640	46717
Range	115276	112821	45965
5% Percentile	63400	78819	752
95% Percentile	178676	191640	46717
95% CI of median			
Actual confidence level	98.08%	98.08%	98.08%
Lower confidence limit	108901	126273	11612
Upper confidence limit	141309	179429	36001
Mean	120782	144611	23829
Std. Deviation	32141	37385	15269
Std. Error of Mean	7374	8577	3503
Lower 95% CI of mean	105290	126592	16470
Upper 95% CI of mean	136273	162630	31189
Coefficient of variation	26.61%	25.85%	64.08%
Geometric mean	116338	139274	15540
Geometric SD factor	1.338	1.343	3.479
Lower 95% CI of geo. Mean	101097	120827	8521
Upper 95% CI of geo. Mean	133876	160537	28341
Harmonic mean	111452	133223	5214
Lower 95% CI of harm. Mean	96371	114903	0
Upper 95% CI of harm. Mean	132128	158493	2589
Quadratic mean	124767	149119	28084
Lower 95% CI of quad. Mean	108653	131750	20856
Upper 95% CI of quad. Mean	139026	164666	33800
Skewness	-0.07498	-0.6131	-0.0853
Kurtosis	-0.02979	-0.7408	-1.351
Sum	2294852	2747608	452756

Attachment 3 - Photographic Randomization

Participant Number	Left Eye	Right Eye
1	X	
2		X
3	X	
4		X
5	X	
6		X
7	X	
9		X
11	X	
12		X
13	X	
14		X
15	X	
16		X
17	X	
18		X
19	X	
20		X
21	X	

ALLERGISA

Attachment 4 - Study Group

PARTICIPANT #	INITIALS	AGE	GENDER	STATUS
001	EHCS	62	F	I
002	PDFS	33	F	I
003	MJC	45	F	I
004	MOPM	56	F	I
005	ELBC	56	F	I
006	JAPP	51	F	I
007	FS	31	F	I
008	ALS	42	F	I
009	SES	52	F	I
010	MMGM	64	F	I
011	RTN	58	F	I
012	LAS	44	F	I
013	CSC	28	F	I
014	MGG	37	F	I
015	AGV	32	F	I
016	SOB	30	F	I
017	VPM	27	F	I
018	AWS	40	F	I
019	MCG	61	F	I
020	GTG	36	F	I

Legend: F: Female / M: Male / NI: Not Included / I: Included / GU: Gave Up

ATTACHMENT 5 - INFORMATION ABOUT THE PRODUCT

The formula for the SPECTRAL.LASH product was submitted by the sponsor and is attached to the printed version of this report. The following pages refer to the formula submitted by the sponsor.