



216 Congers Road, Bldg. 1  
New City, NY 10956 USA  
(845) 634-4330  
FAX: (845) 634-5565  
www.amalabs.com

**A COMPARISON INVESTIGATION INTO THE EFFECT OF TWO FORMULATIONS  
INTENDED TO INCREASE EYELASH DENSITY**

AMA Ref. No.: MS09.EYELASHENH.L5384.SYM

Date: February 3, 2010

Sponsor: Symrise, Inc.  
300 North Street  
Teterboro, New Jersey 07608

1.0 Objective:

The purpose of this study is to evaluate the efficacy of two test products intended to increase eyelash density when tested over a six week period. Image analysis software was used to quantify changes in eyelash density observed in the scientifically matched photographs.

2.0 Test Material:

2.1 Test Sample Description:

On July 16, 2009 two test samples labeled as listed below were received from Symrise, Inc. and assigned AMA Lab Nos. as follows:

AMA Lab Nos.:	Client Nos.:
L-5384	Formula #: 226EL100
L-5385	Formula #: 226EL50

2.1 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test materials were assigned a unique laboratory code numbers and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested.

Samples are retained for a period of three months beyond submission of final report unless otherwise specified by the sponsor or if sample is known to be in support of governmental applications, in which case retained samples are kept two years beyond final report submission.

Sample disposition is conducted in compliance with appropriate federal, state and local ordinances.

2.3 Test Material Evaluation Prerequisite:

Prior to induction of a human test panel, toxicology, microbiology or in-vitro performance spectra may be required to assess the feasibility of commencement as dictated by an Institutional Review Board (IRB) described in Section 3.0.

2.31 Sponsor purports that prior to sample submission to AMA the following tests were conducted with no adverse results and that the test data are on file at their premises and have not been made available to AMA personnel:

- USP or CTFA Preservative Efficacy Test or equivalent
- 90 Day Accelerated Stability and Container Compatibility Study
- Fifty (50) person Repeat Insult Patch Test (RIPT) or equivalent

4.0 Population Demographics:

Number of subjects enrolled .....	4
Number of subjects completing study.....	4
Age Range .....	41 - 52
Sex.....	Female..... 4
Race.....	Caucasian ..... 3
	Hispanic..... 1

4.1 Standards for Inclusion in a Study:

1. Individuals in general good health and free of any dermatological or systemic disorder that would interfere with the results or increase the risks of study participation, at the discretion of the Investigator.
2. Individuals who have completed a preliminary medical history and screening document mandated by AMA Laboratories, Inc.
3. Individuals who have read, understood and signed an informed consent document required by CFR Title 21, Part 50, Subpart B regulations.
4. Individuals able to cooperate with the Investigator and the research staff and are willing to complete the full course of the study.
5. Individuals who understand the instructions for use and are willing to cooperate with the program as stated.
6. Individuals with no known abnormal responses to topically applied products.

#### 4.2 Standards for Exclusion from a Study:

1. Individuals who are under the care of a physician.
2. Individuals who are currently taking any medication that may mask or interfere with the test results at the discretion of the Study Director.
3. Individuals with known allergies or skin and/or eye conditions, which would interfere with the study at the discretion of the Study Director.

#### 4.3 Informed Consent and Medical History:

Prior to initiating the study, a signed informed consent was obtained, in accordance with CFR Title 21, Part 50, Subpart B, from each panelist, describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms are available for inspection on the premises of AMA Laboratories, Inc. only.

#### 4.4 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of AMA Laboratories, Inc., consists of five or more individuals, chosen from within the company for technical expertise and also from the local community for lay interaction. The list of IRB members is kept on file at AMA Laboratories, Inc., and is available for inspection during the hours of operation.

#### 5.0 Methodology:

Four females between the ages of 41 and 52 subjects willing to use the test products daily for 6 weeks were included into this study. The demographic data is shown in Section 4.0. All subjects completed a screening form, medical history form, and informed consent document prior to commencement. In order to pre-condition the test sites and keep the topical treatment consistent during the study, the panelists were required to abstain from using any eyelash and eyebrow conditioning products for a period of 72 hours prior to study commencement. Participants were provided with a daily log and instructed to record the time of each application together with any subjective comments regarding product usage.

The study was conducted according to the sponsor requested design wherein test subjects were divided in two groups. Test products were assigned as follows:

	AMA Lab Nos.:	Client Nos.:	Panelist ID Nos.:
<b>GROUP 1</b>	L-5384	Formula #: 226EL100	629431 648133
<b>GROUP 2</b>	L-5385	Formula #: 226EL50	525216 669598

All subjects were instructed to use the test materials according to the following sponsor supplied use instructions:

*After removing your make-up apply treatment once daily in the evening to the base of the eyelash using provided applicator.*

The application regimen was conducted for a period of 42 consecutive days.

On each evaluation (Baseline, Week 2, Week 4, Week 6) panelists reported with face devoid of any topical treatments. Exclusively detailed, high resolution before and after digital photography was taken, with fixed camera background, distances, angles, settings, lighting, panelist positioning, color bars, white balance, standardized and digitally certified unretouched. Each stage in the progression of the treatment regimen was photographically documented and the test area of involvement isolated.

Photographs were evaluated using image analysis software which allows changes in eyelash density observed to be quantified in the scientifically matched photographs.

## 6.0 Statistical Source Data:

The source data consist of eyelash density calculations performed at Baseline, Week 2, Week 4 and Week 6 evaluation. The data used in the statistical analysis reflects changes from baseline.

## 7.0 Results:

Please refer to the attached Charts and Table.

## 8.0 Archiving:

All original samples, raw data sheets, technician's notebooks, correspondence files, copies of final reports and remaining specimens are maintained on the premises of AMA Laboratories, Inc. in limited access marked storage files. A duplicate DVD copy of final reports is separately archived in a bank safe deposit vault.



Reverse Photo Engineering - Eyelash Density and Length Analysis											
AMA Lab No.: L-5384		Client No.: Formula #: 226EL100								Image Baseline / Day14 / Day 28 / Day 42	
Panelist ID No.:		Eyelash	Baseline [px <sup>2</sup> ]	Day 14 [px <sup>2</sup> ]	% Difference:	Day 28 [px <sup>2</sup> ]	% Difference:	Day 42 [px <sup>2</sup> ]	% Difference:	Image Left	Image Right
GROUP 1	62 9431	Left	118664	173555	46.26%	197447	66.39%	204443	72.29%		
		Right	232438	310478	33.57%	336729	44.87%	373729	60.79%		
	64 8133	Left	183293	243164	32.66%	259274	41.45%	282880	54.33%		
		Right	163400	205550	25.80%	230309	40.95%	266648	63.19%		
Average Density [px <sup>2</sup> ]:			174448.8	233186.8	33.67%	255939.8	46.71%	281925.0	61.61%		
AMA Lab No.: L-5385		Client No.: Formula #: 226EL50								Image Baseline / Day14 / Day 28 / Day 42	
Panelist ID No.:		Eyelash	Baseline [px <sup>2</sup> ]	Day 14 [px <sup>2</sup> ]	% Difference:	Day 28 [px <sup>2</sup> ]	% Difference:	Day 42 [px <sup>2</sup> ]	% Difference:	Image Left	Image Right
GROUP 2	52 5216	Left	296338	343887	16.05%	383534	29.42%	422785	42.67%		
		Right	185886	220227	18.47%	271960	46.30%	295818	59.14%		
	66 9598	Left	191863	205547	7.13%	234143	22.04%	242061	26.16%		
		Right	275630	294590	6.88%	303834	10.23%	309550	12.31%		
Average Density [px <sup>2</sup> ]:			237429.3	266062.8	12.06%	298367.8	25.67%	317553.5	33.75%		



