

# CLINICAL CONSUMER STUDIES

**EYELASH & EYEBROW CONDITIONERS** 



EXPECT THE BEST

# COSMETIC EFFICACY

OF AN EYELASH CONDITIONER

# **ABSTRACT**

The Benchmarking Company (TBC) was engaged by Athena Cosmetics, Inc. to conduct a 42-day Beauty Product Testing Group (BPT) to test the cosmetic efficacy and appeal of RevitaLash® Advanced Eyelash Conditioner. A subjective evaluation of cosmetic efficacy and tolerance was obtained with a questionnaire that was completed by the volunteer subjects at three data points; Baseline Day 1, Day 21 and Day 42 upon completion of the study.

# STUDY DESIGN

Sixty-three (63) participants tested this product over 42 consecutive days, with online self-assessment evaluation surveys fielded after Day 1, Day 21, and Day 42. TBC recruited all BPT panelists from its proprietary PinkPanel database.

In order to qualify to participate, all respondents met the following criteria:

- A. Must be female.
- **B.** Must be aged 30-50.
- **C.** Subjects must be able to understand their role in the study, able to provide written Informed Consent for study, and able to fully participate in the study (42 days consecutively).

Questionnaires to evaluate the appeal and effectiveness of the product were given to the subjects at the beginning, middle and at the end of the study (intervals noted above and were delivered consecutively throughout the 42-day period) to evaluate the benefits and overall user experience.

This study was conducted in compliance with the CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study.

TBC recruited participants from across the United States, excluding California.

A total of 63 subjects were recruited for this study.

Each of the volunteer subjects was instructed to apply the product once/day for a period of 42 consecutive days. On each evaluation time point (Baseline Day 1, Day 21, and Day 42) participants were asked to complete a digital Self-Assessment Questionnaire. The data used in the statistical analysis reflects changes from baseline.

Revital ash ADVANCED

# **RESULTS**

#### **Eyelash Product Questionnaire Summary**

#### After 3 Weeks of Use:

94% Improves the overall appearance of my eyelashes

94% My eyelashes are healthier-looking

92% My lashes feel stronger

89% My eyelashes look more attractive

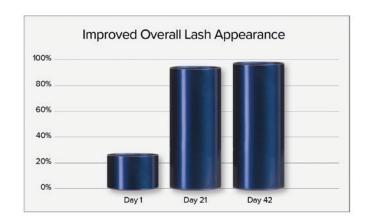
#### After 6 Weeks of Use:

98% Improves the overall appearance of my eyelashes

98% My eyelashes are healthier-looking

98% My lashes feel stronger

95% My eyelashes look more attractive





# **CONCLUSION**

98%

of study participants agreed that after using the test product for 6 weeks, the overall appearance of their eyelashes improved.

#### **Acknowledgements**

The Benchmarking Company

Denise Herich

Co-Founder & Managing Partner

Jennifer Stansbury

Co-Founder & Managing Partner

# CLINICAL EVALUATION

TO DETERMINE THE OCULAR SAFETY, IRRITATION POTENTIAL AND COSMETIC EFFICACY OF AN EYELASH CONDITIONER

# **ABSTRACT**

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To many women, the appearance of eyelashes is very important. Athena Cosmetics, Inc. has been a pioneer in the development of cosmetic eyelash conditioners intended to enhance the appearance of eyelashes. The purpose of this clinical study was to evaluate the ocular safety, tolerance and cosmetic efficacy of a novel eyelash conditioner developed by Athena Cosmetics that was launched commercially as RevitaLash® Advanced (referred to herein as the "Test Product").

A total of 19 women subjects completed this 28-day clinical study conducted by an independent laboratory, EvaluLab. Subjects were clinically evaluated by a certified Ophthalmologist at the beginning and end of the study (Day 28).

Subjects applied the Test Product once/day to the eyelashes of each eye for 28 days. On Day 28, subjects completed questionnaires to rate tolerance and effect of the Test Product on the appearance of their eyelashes.

Clinical evaluation determined no adverse reactions or significant changes to intraocular pressure after 28 days of daily use of the Test Product. Subjects' self-evaluation also determined that the Test Product was well-tolerated by the subjects with only temporary (2-3 days) irritation reported by 4 subjects.

Subjects reported in questionnaires substantial improvement in the appearance of their eyelashes.

# STUDY DESIGN

This was a 28-day, single site, open-label study to assess the ocular safety, tolerance and cosmetic efficacy of a new formula of an eyelash conditioner (Test Product). A total of 19 healthy, adult women between the ages of 18 and 60 years (mean age = 34.2 yrs), completed the study. All subjects signed an IRB-approved consent form prior to participating in the study.

Subjects applied the product to the upper eyelashes of each eye once/day.

ocular safety: At the beginning of the study, on Day 0, each subject was clinically evaluated by a board-certified Ophthalmologist. The ocular examination involved a slit lamp evaluation of the subject's eyelids, cornea, conjunctiva, anterior chambers, papillary reactions and visual acuity. In addition, the intraocular pressure

(IOP) of each eye was measured by the study Ophthalmologist. The clinical examination and IOP measurement was repeated by the study Ophthalmologist at the end of the study on Day 28.

**TOLERANCE:** Subjects were instructed to monitor and record any adverse reactions experienced throughout the study. At the end of the study (Day 28), each subject completed a self-evaluation questionnaire that included questions about tolerability.

by subjects' self-evaluations of the effect of the product on the appearance of their eyelashes using the questionnaire that was completed at the end of the study on Day 28. Subjects also rated the Test Product on ease of application and sensory attributes of the Test Product.

# **RESULTS**

**OCULAR SAFETY:** There were no Adverse Events or Serious Adverse Events reported by the study Ophthalmologist on Day 28 of the study. Also, there was no statistically significant change in mean IOP between Day 0 and Day 28.

**TOLERANCE:** The Test Product was well tolerated by all of the subjects. No signs of irritation were noted by the study Ophthalmologist on Day 28 and 79% of the subjects reported on their questionnaires that they had no intolerance to the Test Product. "Slight" temporary irritation for 2 days was reported by 3 subjects and one subject reported 3 days of irritation.

**COSMETIC EFFICACY:** The following results were obtained from the subjects' self-evaluation on questionnaires, completed on Day 28 of the study:

- 32% Observed changes in appearance of their eyelashes within 14 days of using the Test Product.
- 68% Reported improvement in the appearance of their eyelashes within four weeks (See Fig. 1).
- 94% Reported they appreciated the "Ease of Application" of the Test Product.



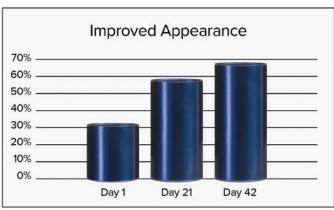


Figure 1. Subjects' self-evaluations of changes in appearance of eyelashes after use of Test Product for 28 days.

# **CONCLUSIONS**

- The Test Product was demonstrated to be safe to the eyes. The study Ophthalmologist reported no adverse reactions in any subject after daily use of the Test Product for 28 days and no significant change in IOP.
- Subjects' self-evaluations indicated the Test Product was well-tolerated with only temporary irritation reported by just 4 subjects.
- The testing laboratory concluded the Test Product was "non-irritant to the eyes" and is "considered safe for use as an eyelash conditioner."
- Subjects found the Test Product to be highly effective in improving the appearance of their eyelashes.

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#### **ABSTRACT**

The objective of this clinical study was to determine the irritation and sensitization (contact allergy) potential of a cosmetic eyelash

conditioner formula after repeated application to the skin of human subjects.

# STUDY DESIGN

A total of 52 subjects, ranging in age from 18 to 59 years old, were enrolled in the clinical study, and 51 of those subjects completed the study. Of the subjects completing the study, 48 were female and 3 were male. Prior to the initiation of the study, an Informed Consent was obtained from each volunteer.

Subjects were requested to bathe or wash as usual before arrival to the facility. Patches containing the test material were then affixed directly to the skin of the intra-scapular regions of the back, to the right or left of the midline, and subjects were dismissed with instructions not to wet or expose the test area to direct sunlight.

Subjects were instructed to remove the patches approximately 48 hours after the first application and 24 hours thereafter for the remainder of the study.

This procedure was repeated until a series of

nine (9) consecutive, 24-hour exposures had been made three (3) times a week for three (3) consecutive weeks. Prior to each reapplication, the test sites were evaluated by trained laboratory personnel.

Following a 10-14 day rest period, a retest/challenge dose was applied once to a previously unexposed test site. Test sites were evaluated by trained laboratory personnel 48 and 96 hours after application.

In the event of an adverse reaction, the area of erythema and/or edema were measured. Subjects were instructed to report any delayed reactions that might occur after the final reading.

The scoring scale and definition of terms such as erythema, edema, induration, and vesiculation are based upon the scoring scheme developed by the International Contact Dermatitis Research Groupscoring scale.\*

 $^*Rietschel,\,R.L.,\,Fowler,\,J.F.,\,Ed.,\,Fisher's\,\,Contact\,\,Dermatitis\,\,(fourth\,\,ed.).\,\,Baltimore,\,Williams\,\,\&\,\,Wilkins,\,1995$ 

# **RESULTS & CONCLUSIONS**

- Under conditions of the study, there were no identifiable signs or symptoms of sensitization (contact allergy) noted for the tested eyelash conditioner.
- No adverse reactions of any kind were reported during the course of this study.

#### Acknowledgements

BioScreen® Testing Services, Inc., Torrance, CA
Mary Fredenberg, M.D.
Consulting Dermatologist
Mallyc Murray
Quality Assurance Supervisor
Hemali B Gunt, P.h.D.
Clinical Manager

#### SUMMARY

- Dermatologist reviewed
- Ophthalmologist reviewed
- Hypoallergenic

surface of the eye

- Non-irritating
- Safe for use with contact lenses
- Safe for use on the eyelashes [1]

  Formulated with a cosmetic thickener so product stays where applied no seeping onto the

Clinical tests show no effect on intraocular pressure [2]

Contains a powerful cosmetic anti-microbial to prevent bacteria buildup inside the tube, allowing for repeated use of single applicator

- Dramatic changes in eyelash appearance In consumer studies:
- 98% Reported the overall appearance of eyelashes improved in 6 weeks [3] 94% Reported improvement in eyelash appearance within just 3 weeks! [4]
- Granted US PATENT for The Curl Effect®

The proprietary technology found in RevitaLash® Advanced Eyelash Conditioner has been patented in the United States. This provides loyal users confidence that our proprietary formula delivers the absolute best in eyelash beauty and product innovation [5]

- Consumers like ease of application Only need a single application wand convenient cosmetic applicator 100% Reported the product was easy to use [6]
- Convenient cosmetic for physicians and their patients

Patients can buy RevitaLash® Advanced directly from physicians and their staff

- [1] Evalulab Study, January 2010
- [2] Evalulab Study, January 2010
- [3] The Benchmarking Company Beauty Product Testing Study, November 2014[4] The Benchmarking Company Beauty Product Testing Study, November 2014
- [5] U.S. Patent No. 9,006,291 B2, April 2015
- [6] The Benchmarking Company Beauty Product Testing Study, November 2014





REVITALASH® ADVANCED

# COSMETIC EFFICACY

OF AN EYEBROW CONDITIONER

# **ABSTRACT**

The Benchmarking Company (TBC) was engaged by Athena Cosmetics, Inc. to conduct a 56-day Beauty Product Testing Group (BPT) to test the cosmetic efficacy and appeal of the RevitaBrow® Advanced Eyebrow Conditioner. A subjective evaluation of cosmetic efficacy and tolerance was obtained with a questionnaire that was completed by the volunteer subjects at four data points: Baseline Day 1, Day 21, Day 42 and Day 56 upon completion of the study.

### STUDY DESIGN

One hundred twelve (112) participants tested this product over 56 consecutive days, with online self-assessment evaluation surveys fielded after Day 1, Day 21, Day 42 and Day 56. TBC recruited all BPT panelists from its proprietary PinkPanel and GuysthatGroom databases.

In order to qualify to participate, all respondents met the following criteria:

- **A.** Must be aged 25-50.
- **B.** Must not be currently undergoing a medical treatment that may cause hair to fall out, such as chemotherapy.
- C. Must not currently use an eyebrow conditioning product.
- D. Subjects must be able to understand their role in the study, able to provide written Informed Consent for study, and able to fully participate in the study (56 days consecutively).

Questionnaires to evaluate the appeal and effectiveness of the product were given to the subjects at the beginning, middle and at the end of the study (intervals noted above and were delivered consecutively throughout the 56-RevitaBrow ADVANCED day period) to evaluate the benefits and overall user experience.

This study was conducted in compliance with the CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study.

TBC recruited participants from across the **United States** 

A total of 112 subjects were recruited for this study and included both male and female participants.

Each of the volunteer subjects was instructed to apply the product once/day for a period of 56 consecutive days. On each evaluation time point (Baseline Day 1, Day 21, Day 42 and Day 56) participants were asked to complete a digital Self-Assessment Questionnaire. The data used in the statistical analysis reflects

changes from baseline.

RevitaBrow. ADVANCED

**RESULTS** 

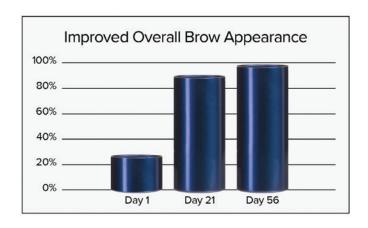
#### **Eyebrow Product Questionnaire Summary**

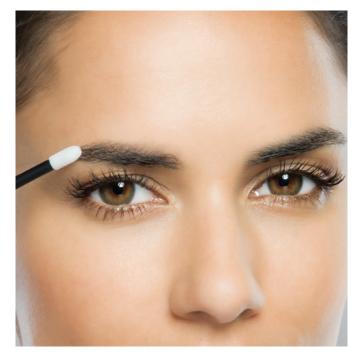
#### After 3 Weeks of Use:

- 89% Improves the overall appearance of my eyebrows
- 87% I prefer the look of my eyebrows now vs. before I started using the conditioner
- 81% My eyebrows look more defined
- 80% My brows are fuller-looking

#### After 8 Weeks of Use:

- 96% Improves the overall appearance of my eyebrows
- 95% I prefer the look of my eyebrows now vs. before I started using the conditioner
- 94% My eyebrows look more defined
- 92% My brows are fuller-looking





# CONCLUSION

of study participants agree or strongly agree that after using the test product for 8 weeks, the overall appearance of their eyebrows improved.

#### **Acknowledgements**

The Benchmarking Company

Denise Herich

Co-Founder & Managing Partner

Jennifer Stansbury Co-Founder & Managing Partner

# **EVALUATION / HRIPT**

**HUMAN REPEAT INSULT PATCH TEST FOR SKIN IRRITATION & SKIN SENSITIZATION** 

# REVITABROW® ADVANCED

**EYEBROW CONDITIONER** 

# **ABSTRACT**

The objective of this clinical study conducted by BioScreen® Testing Services, Inc. was to determine the irritation and sensitization (contact allergy) potential of a cosmetic eyebrow conditioner formula after repeated application to the skin of human subjects.

#### STUDY DESIGN

A total of 52 subjects, ranging in age from 18 to 59 years old, were enrolled in the clinical study, and 51 of those subjects completed the study. Of the subjects completing the study, 48 were female and 3 were male. Prior to the initiation of the study, an Informed Consent was obtained from each volunteer.

Subjects were requested to bathe or wash as usual before arrival to the facility. Patches containing the test material were then affixed directly to the skin of the intra-scapular regions of the back, to the right or left of the midline, and subjects were dismissed with instructions not to wet or expose the test area to direct sunlight.

Subjects were instructed to remove the patches approximately 48 hours after the first application and 24 hours thereafter for the remainder of the study.

This procedure was repeated until a series of

nine (9) consecutive, 24-hour exposures had been made three (3) times a week for three (3) consecutive weeks. Prior to each reapplication, the test sites were evaluated by trained laboratory personnel.

Following a 10-14 day rest period, a retest/ challenge dose was applied once to a previously unexposed test site. Test sites were evaluated by trained laboratory personnel 48 and 96 hours after application.

In the event of an adverse reaction, the area of erythema and/or edema were measured. Subjects were instructed to report any delayed reactions that might occur after the final reading.

The scoring scale and definition of terms such as erythema, edema, induration, and vesiculation are based upon the scoring scheme developed by the International Contact Dermatitis Research Group scoring scale.\*

\*Rietschel, R.L., Fowler, J.F., Ed., Fisher's Contact Dermatitis (fourth ed.). Baltimore, Williams & Wilkins, 1995

# RESULTS & CONCLUSIONS

- Under conditions of the study, there were no identifiable signs or symptoms of sensitization (contact allergy) noted for the tested eyebrow conditioner.
- No adverse reactions of any kind were reported during the course of this study.

#### Acknowledgements

Clinical Supervisor

BioScreen\* Testing Services, Inc., Torrance, CA Mary Fredenberg, M.D. Consulting Dermatologist Theresa Johnson Quality Assurance Manager Brochelle Yazzie

### **SUMMARY**

- Dermatologist reviewed
- Hypoallergenic
- Non-irritating
- Safe for use on the eyebrows

Formulated with a cosmetic thickener so product stays where applied - no seeping

Contains a powerful cosmetic anti-microbial to prevent bacteria buildup inside the tube. This allows for repeated use of single applicator.

Safety tests show no adverse reactions of any kind reported during skin irritation and sensitization evaluation [1]

- Dramatic changes in eyebrow appearanceIn consumer studies:
- 96% Reported preferring the look of their eyebrows now vs. before starting to use the conditioner  $^{\text{[2]}}$
- 89% Reported improvement in eyebrow appearance within just 3 weeks! [3]

#### Consumers like ease of application

Unique doe-foot applicator provides control and ease of use to follow natural contours of eyebrows

Only need a single application wand – convenient cosmetic applicator

98% Reported product was easy to apply with precision  $^{[4]}$ 

# Convenient cosmetic for physicians and their patients

Patients can buy RevitaBrow® Advanced directly from physicians and their staff

<sup>[4]</sup> The Benchmarking Company Beauty Product Testing Study, May 2016



REVITABROW® ADVANCED

<sup>[1]</sup> BioScreen Testing Services Inc. August 2014

<sup>[2]</sup> The Benchmarking Company Beauty Product Testing Study, May 2016

<sup>[3]</sup> The Benchmarking Company Beauty Product Testing Study, May 2016



# **COMPANY**

Manufactured by Athena Cosmetics, Inc., the RevitaLash® Cosmetics brand is a pioneer and worldwide leader in advanced lash, brow and hair beautification products. These luxury cosmetic products are produced in the United States and can be found in over 10,000 high end spas, medi-spas, doctor's offices, and specialty boutiques throughout the domestic market and in over 60 countries worldwide.

In 2006, when Athena unveiled its groundbreaking hero product it swept the beauty industry, uncovering a passionate consumer demand for cosmetic eyelash beautification products. The introduction of the original formula created an entirely new category of innovative lash conditioning products.

Today, RevitaLash® Cosmetics continues a legacy of innovation with the introduction of RevitaLash® Advanced and RevitaBrow® Advanced and the expansion into the fine and thinning hair category, solidifying their position as the lash, brow, hair beauty experts.

RevitaLash® Cosmetics takes pride in their commitment to research and development, safety testing and quality assurance with a portfolio of products that meet the highest level of cosmetic standards.

# **HISTORY**

Ten years ago, Dr. Michael Brinkenhoff created a very special gift for his wife Gayle, to help her feel beautiful again after the tolls of breast cancer and chemotherapy impacted the natural beauty of her eyelashes. Using his experience as a practicing Ophthalmologist for over 25 years, Dr. Brinkenhoff developed a cosmetic formula to help revitalize and restore the strength and beauty of her natural eyelashes.

With the creation of this beauty breakthrough, an entirely new and unique cosmetic product was born. Today, this lash, brow and fine and thinning hair cosmetic range helps women around the world feel confident in their natural beauty.

An avid philanthropic supporter of breast cancer research education and initiatives, RevitaLash® Cosmetics donates annually to City of Hope® and raises money to help increase awareness of the devastating disease, giving back to the community from which it was born.

"Often we feel helpless when someone we love is suffering. I am very fortunate, in my own small way, to have been able to help Gayle through her recovery. Watching her excitement about her beautiful looking eyelashes was a real joy."

- Michael Brinkenhoff, M.D.





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