

EVALUATION OF A COSMETIC BROW PRODUCT FOR WATER RESISTANCE AND TRANSFER PROOF CLAIM

FINAL REPORT

July 15, 2015

SPONSOR: IP Brands LLC

20-21 Wagaraw Road Fair Lawn, NJ 07410

TEST PRODUCTS: Brow Gel (Blonde, Brunette and Dark Brunette)

STUDY NUMBER: BCS 15-041

PROJECT NUMBER: 906572

RESEARCH STANDARD

This clinical study was conducted in accordance with the International Conference of Harmonization Tripartite Guideline on Good Clinical Practice, applicable FDA regulations/ guidelines set forth in 21 CFR Parts 11, and 50 and standard practices of BioScreen Testing Services.

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I. STUDY CONCLUSIONS

Under the conditions of the study and based on the study results, the following claims were substantiated for <u>Test Product</u>: <u>Brow Gel (Blonde, Brunette and Dark Brunette)</u>:

- 1) Excellent water resistance properties post 60 second water immersion.
- 2) Excellent transfer proof properties

II. SUMMARY OF RESULTS

A total of 27 healthy female subjects ranging between 20-64 years of age were consented, enrolled, and completed the 1-day clinical study.

A. Transfer Proof

Scale: 0= No Transfer, 1 = Mild Transfer, 2 = Moderate Transfer; 3 = Severe Transfer

Parameter	20 Minutes Post-Product Application	
Average score for transfer proof property	0.00	
% of subjects showing results in favor of the no transfer proof property	100.00%	

BOLD values indicate statistical significance ($p \le 0.05$)

Clinical Findings

• 100.00% of the subjects showed no transfer of the test product post-application.

B. Water Resistance

Scale: 0 = No water resistance

1 = Poor water resistance

2 = Good water resistance

3 =Excellent water resistance

Parameter	Post 1 Minute Water Immersion
Average score for water resistance property	3.00
% of subjects showing results in favor of excellent water resistance property	100.00%

BOLD values indicate statistical significance ($p \le 0.05$)

Clinical Findings

• 100.00% of the subjects showed excellent water resistance properties post water immersion.

C. Post Treatment Questionnaire

SCALE: 1= Strongly Agree, 2= Agree, 3= Disagree

Parameter	% of Subjects with Favorable Responses (30 Minutes Post- Application)
1. Within minutes of application, the Brow Formula enhances my overall appearance.	88.89%
2. Within minutes of application, the Brow formula helps my eyebrows appear fuller.	100.00%
3. Within minutes of application, the Brow formula helps my eyebrows appear more defined.	96.30%
4. Within minutes of application, the Brow formula provides natural looking brows.	92.59%
5. Within minutes of application, the Brow formula helps my brows look more polished.	92.59%
6. Within minutes of application, the Brow formula helps me to appear younger	66.67%
7. Within minutes of application, the Lasting Effects Brow Gel covered my eyebrow imperfections.	96.30%

SCALE: 1= Strongly Disagree, 2= Disagree, 3= Agree, 4 = N/A

Parameter Parameter	% of Subjects with Favorable Responses (48 Hours Post-Application)
1. The Brow formula lasted for more than 24 hours.	96.30%
2. The Brow formula lasted for 48 hours.	74.07%
3. The Brow Formula enhances my overall appearance.	85.19%
4. The Brow formula helps my eyebrows appear fuller.	100.00%
5. The Brow formula helps my eyebrows appear more defined.	96.30%
6. The Brow formula provides natural looking brows.	92.59%
7. The Brow formula helps to hold my hairs in place giving the appearance of more groomed brows.	96.30%
8. The brow formula helps my brows look more polished.	92.59%

9. The Brow formula helps me appear younger.	70.37%
10. The Brow formula helps to cover grey hairs.	100.00%
11. The Brow formula is superior to other brow products that I have used.	66.67%
12. I would recommend Lasting Effects Brow Gel to your friends?	88.89%
13. The Lasting Effects Brow Gel covered my eyebrow imperfections.	92.59%
14. The Brow formula stayed in place throughout the day.	100.00%
15. The Brow formula lasted for days.	77.78%
16. The Brow formula performs better than a brow pencil.	95.24%
17. The Brow formula performs better than a brow powder.	85.71%
18. The Brow formula lasts all day.	100.00%

III. STUDY OBJECTIVE

To evaluate the efficacy of a brow gel for the following attributes:

- 1) Water resistance
- 2) Transfer proof

To evaluate the effectiveness of a brow gel for long wear based on consumer perception.

IV. STUDY DATES

The study began on July 7, 2015 and completed on July 9, 2015.

V. TESTING FACILITY

BioScreen Clinical Services Division BioScreen Testing Services, Inc. 3305 N. 2nd Street, Phoenix, AZ 85012

VI. TEST PRODUCTS

The date and quantity of individual test samples received from IP Brands LLC are listed below with their assigned accession number.

Test Sample Name	Date Received	Quantity Received	Accession Number
Brow Gel (Blonde)	6/29/2015	12	906572
Brow Gel (Brunette)	6/29/2015	8	906573
Brow Gel (Dark Brunette)	6/29/2015	12	906574

VII. TEST PRODUCT HANDLING

Test products that had been reviewed and approved for use by the Regulatory and Safety representatives of IP Brands LLC were tested.

Upon arrival at BioScreen Clinical Services (BCS) the test products were assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested.

Samples will be retained for a period of 30 days beyond submission of final report. Sample disposition will be conducted in compliance with appropriate federal, state and local ordinances

VIII. STUDY PARTICIPATION RECRUITMENT

Panel selection was accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof.

IX. INFORMED CONSENT, PHOTGRAPHY RELEASE AND MEDICAL HISTORY FORMS

Informed consent was obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists signed and dated the informed consent document a photography release form to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and complete an extensive medical history form. These forms along with the signed consent forms are available for inspection on the premises of BCS only.¹

X. INCLUSION CRITERIA

- 1. Female
- 2. Age: 18-65
- 3. Race: Unrestricted
- 4. Individuals who were in good general health.
- 5. Individuals who were free of any dermatological or systemic disorder, which would interfere with the results, at the discretion of the Investigator.
- 6. Individuals who completed a preliminary medical history and who read, understood and signed an informed consent document.
- 7. Individuals who were able to cooperate with the Investigator and research staff, had test product applied according to the protocol, and completed the full course of the study.
- 8. Individuals who did not concurrently participate or had participated in any other clinical study involving the same test sites (face and forearm) for the past 15 days.
- 9. Individuals who agreed not to wash their face after application of the test product for 48 hours.

XI. EXCLUSION CRITERIA

- 1. Individuals who had a history of any acute or chronic disease that could interfere with or increase the risk on study participation.
- 2. Individuals with an active (flaring) disease or chronic skin allergies (atopic dermatitis/eczema), or had recently treated skin cancer (within the last 12 months).

- 3. Individuals with damaged skin at or in close proximity to test site (e.g., sunburn, tattoos, scars, excessive hair, piercings or other disfigurations).
- 4. Individuals who had any history, which, in the Investigator's opinion, indicated the potential for harm to the subject or placed the validity of the study in jeopardy.
- 5. Individuals who indicated that they were pregnant, planning a pregnancy or nursing.
- 6. Individuals who had a known history of hypersensitivity to any cosmetics, personal care products and/or fragrances.
- 7. Individuals who were employees of BioScreen

XII. EXPERIMENTAL TECHNIQUES

Clinical grading for water resistance properties

Each subject had the test sites (volar forearm) evaluated by a trained BCS staff member for the following parameter based on the following scale:

- 0 = No water resistance (Severe running)
- 1 = Poor water resistance (Moderate running)
- 2 = Good water resistance (Slight running)
- 3 = Excellent water resistance (No running)

Clinical grading of transfer proof properties

A lint free wipe was pressed against a pre-determined test site on the forearm. The transfer on the lint wipe was graded according to the following scale: (Half point increments will be used)

0 = No Transfer. 1 = Mild Transfer, 2 = Moderate Transfer; 3 = Severe Transfer

Self-Assessment Questionnaire

Each subject was instructed to complete a self-assessment questionnaire, provided by the Sponsor, at the Immediate and 48 hour post-treatment intervals.

XIII. PROCEDURE

- 1. Prospective subjects reported to the facility at the start of the study.
- 2. Prospective subjects were instructed to wear clothing that did not cover their forearms.
- 3. Prior to beginning all study related activities, prospective subjects completed an informed consent form, medical history form and a HIPAA form.
- 4. Subjects were instructed to cleanse their face with a neutral soap and gently

- pat dry with a paper towel. The volar surface of the forearms was gently wiped with a damp disposable washcloth and patted dry with a paper towel by trained BCS staff.
- 5. Trained BCS staff marked one test site on each volar forearm surface such that one site served to test water resistance and one served to test transfer proof (based on a computer generated randomization). There were no control sites. Each test site was 3cm X 3cm. Test site was placed centrally on the forearm (at least 2cm from the wrist joint and at least 2cm from elbow joint). See schematic representation of test site, Figure 1.
- 6. Trained BCS staff applied the test product evenly and moderately to each test site area. Subjects were instructed to keep their volar forearm uncovered/exposed for the entire study duration. Subjects were not allowed to cover or wet or wipe their volar forearm for the water resistance portion for the study duration.
- 7. Subjects were instructed to apply the test product to their eyebrows per Sponsor use instructions.
- 8. At 20 minutes (± 5 minutes) post-application to the test sites (forearms), BCS staff member applied a lint free wipe to one test site and wipe once. Trained BCS staff member graded and documented any observations of the test product transfer. The following scale was used to grade the transfer properties of the product):

Scoring Scale:

- 0 = No Transfer
- 1 = Mild Transfer
- 2 = Moderate Transfer
- 3 = Severe Transfer
- 9. At 30 minutes (± 10 minutes) post application, subjects were asked to place the second test site under running luke warm water (a gentle stream ensuring no pressure will be exerted on the test site) for 1 minute under supervision of a trained BCS staff member. Following running luke warm water bath, a trained BCS staff member graded and documented any observations of the test product running. The following scale was used to grade the water resistant properties of the product:

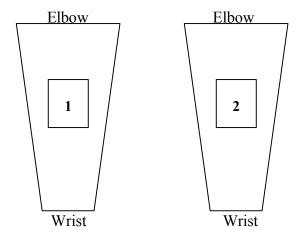
Scoring Scale:

- 0 = No water resistant (severe running)
- 1 = Poor water resistant (moderate running)
- 2 = Good water resistant (mild running)
- 3 = Excellent water resistant (no running)
- 10. Subjects were also instructed to fill out a post-treatment questionnaire.
- 11. Subjects were instructed to not wash their face until after completion of the 48 hour measurement.
- 12. Subjects were then dismissed from the facility and were instructed to return 48

hours (\pm 30 minutes) post-treatment.

- 13. At 48 hours (± 30 minutes), subjects were instructed to complete a post-treatment questionnaire.
- 14. Subjects were then be dismissed after the 48 hour questionnaire had been completed.

Figure 1: Schematic representation of test sites for volar forearm.



XIV. ADVERSE EVENTS

There were no test product related adverse events reported during study period.

XV. STUDY RESULTS AND ANALYSIS

A total of 27 female subjects, consented, enrolled, and completed the 1 day clinical study.

Table 1. Subject Demographics

No.	Subject ID	Subject Initials	Age	Race
1	450	VAG	33	Н
2	3260	RMR	59	Н
3	3421	GRR	36	Н
4	3756	NCS	54	С
5	4119	SLC	61	С
6	4690	MDB	37	С
7	4736	TMT	38	AA
8	6245	QCH	38	AA
9	7239	AEF	33	С
10	8907	ARB	38	С
11	9502	CET	28	С
12	10359	G-C	39	Н
13	12388	KAM	41	Н
14	15339	EMG	32	Н
15	15676	EGO	33	С
16	15718	A-M	28	Н
17	16218	ANL	28	AA
18	16419	D-D	41	Н
19	16991	KAB	41	С
20	17266	JAR	34	С
21	17317	KJP	56	С
22	18155	NLF	47	С
23	19535	JNK	64	С
24	19538	ASM	20	Н
25	19600	C-Q	27	Н
26	19775	DLE	58	С

No.	Subject ID	Subject Initials	Age	Race
27	19995	D-N	51	С

AA=African American, C = Caucasian, H= Hispanic

B. Transfer Proof Properties

Table 2. Product transfer scores

Scale: 0 = No Transfer. 1 = Mild Transfer, 2 = Moderate Transfer; 3 = Severe Transfer

No.	Subject ID	Evaluator Scores
1100	Subject 12	20 Minutes Post Test Product Application
1	450	0
2	3260	0
3	3421	0
4	3756	0
5	4119	0
6	4690	0
7	4736	0
8	6245	0
9	7239	0
10	8907	0
11	9502	0
12	10359	0
13	12388	0
14	15339	0
15	15676	0
16	15718	0
17	16218	0
18	16419	0
19	16991	0
20	17266	0
21	17317	0

No.	Subject ID	Evaluator Scores
110.		20 Minutes Post Test Product Application
22	18155	0
23	19535	0
24	19538	0
25	19600	0
26	19775	0
27	19995	0
Mean ± SD		0.00 ± 0.00

Table 3. Descriptive statistics of transfer proof property.

Parameter	None	Mild	Moderate	Severe
Number of Subjects	27	0	0	0
Percent of Subjects	100.00%	0.00%	0.00%	0.00%

C. Water Resistant Properties

Table 4. Water resistant scores after 1 minute under luke warm water.

Scale: 0 = No water resistance

1 = Poor water resistance

2 = Good water resistance

3 = Excellent water resistance

No.	Subject ID	Evaluator Scores
140.	Subject ID	Post 1 Minute Water Immersion
1	450	3
2	3260	3
3	3421	3
4	3756	3
5	4119	3
6	4690	3
7	4736	3
8	6245	3
9	7239	3
10	8907	3
11	9502	3
12	10359	3
13	12388	3
14	15339	3
15	15676	3
16	15718	3
17	16218	3
18	16419	3
19	16991	3

Na	Cubicot ID	Evaluator Scores
No.	Subject ID	Post 1 Minute Water Immersion
20	17266	3
21	17317	3
22	18155	3
23	19535	3
24	19538	3
25	19600	3
26	19775	3
27	19995	3
	Mean ± SD	3.00 ± 0.00

Table 5. Descriptive statistics of water resistance property.

Parameter	Excellent	Good	Poor	None
Number of Subjects	27	0	0	0
Percent of Subjects	100.00%	0.00%	0.00%	0.00%

APPENDIX

A) Post Treatment Questionnaire (20 Minutes Post-Application)

SCALE: 1= Strongly Agree, 2= Agree, 3= Disagree

Subject ID	1. Within minutes of application, the Brow Formula enhances my overall appearance.	2. Within minutes of application, the Brow formula helps my eyebrows appear fuller.	3. Within minutes of application, the Brow formula helps my eyebrows appear more defined.	4. Within minutes of application, the Brow formula provides natural looking brows.	5. Within minutes of application, the Brow formula helps my brows look more polished.	6. Within minutes of application, the Brow formula helps me to appear younger	7. Within minutes of application, the Lasting Effects Brow Gel covered my eyebrow imperfections.
450	1	1	1	1	1	1	1
3260	2	2	2	2	2	2	2
3421	2	2	2	2	2	2	2
3756	2	2	2	2	2	3	2
4119	1	1	1	2	2	2	1
4690	1	1	1	1	1	1	1
4736	2	1	3	3	2	3	3
6245	1	1	1	1	1	1	1
7239	1	1	1	1	1	1	1
8907	1	1	1	1	1	2	1
9502	3	1	2	3	3	3	2
10359	1	1	1	2	2	2	2
12388	2	2	2	2	2	3	2
15339	2	2	2	2	2	2	2

15676	3	1	1	2	1	3	1
15718	1	1	1	1	1	2	1
16218	3	2	2	2	3	3	2
16419	2	1	1	1	1	2	1
16991	2	2	2	2	2	2	2
17266	2	1	1	2	1	3	1
17317	2	1	2	1	2	2	2
18155	1	1	1	1	1	2	2
19535	2	2	2	2	2	3	2
19538	2	2	2	2	2	3	2
19600	1	1	1	1	1	1	1
19775	1	1	1	2	1	1	1
19995	2	2	1	2	2	2	2

B) Post Treatment Questionnaire (48 Hours Post-Application)

SCALE: 1= Strongly Agree, 2= Agree, 3= Disagree, 4= N/A

Subject ID	1. The Brow formula lasted for more than 24 hours.	2. The Brow formula lasted for 48 hours.	3. The Brow Formula enhances my overall appearance.	4. The Brow formula helps my eyebrows appear fuller.	5. The Brow formula helps my eyebrows appear more defined.	6. The Brow formula provides natural looking brows.	7. The Brow formula helps to hold my hairs in place giving the appearance of more groomed brows.	8. The brow formula helps my brows look more polished.	9. The Brow formula helps me appear younger.
450	1	2	2	2	2	2	2	2	2
3260	2	3	2	2	2	2	2	2	2
3421	1	2	1	1	2	2	1	1	2
3756	2	2	2	2	2	2	2	2	2
4119	1	1	1	1	1	1	1	1	2
4690	2	3	2	2	2	2	2	2	2
4736	3	3	3	2	3	2	2	3	3
6245	1	2	1	2	1	2	2	2	2
7239	1	2	1	1	1	1	1	1	1
8907	1	2	1	1	1	1	1	1	2
9502	1	2	1	1	1	2	1	2	3
10359	1	1	2	1	1	2	1	2	2
12388	2	2	2	2	2	2	2	2	3

15339	1	1	2	2	2	2	2	2	2
15676	2	3	3	1	1	2	1	1	3
15718	1	2	1	1	1	1	1	1	2
16218	2	3	3	2	2	3	3	3	3
16419	1	3	2	1	1	1	1	1	2
16991	1	1	2	1	2	2	2	2	2
17266	1	1	1	1	1	2	1	2	3
17317	1	2	2	1	1	2	2	2	2
18155	1	2	2	1	1	1	2	2	2
19535	1	1	3	2	2	2	2	2	3
19538	1	2	2	2	2	3	2	2	3
19600	2	3	1	1	1	1	1	1	1
19775	1	1	1	1	1	1	1	1	1
19995	2	2	2	1	1	1	2	2	2

Subject ID	10. The Brow formula helps to cover grey hairs.	11. The Brow formula is superior to other brow products that I have used.	12. I would recommend Lasting Effects Brow Gel to your friends?	13. The Lasting Effects Brow Gel covered my eyebrow imperfections.	14. The Brow formula stayed in place throughout the day.	15. The Brow formula lasted for days.	16. The Brow formula performs better than a brow pencil.	17. The Brow formula performs better than a brow powder.	18. The Brow formula lasts all day.
450	4	1	1	1	1	1	1	1	1
3260	2	2	2	2	2	2	2	2	2
3421	4	3	1	1	1	2	1	1	1
3756	2	3	2	2	2	3	2	2	2
4119	1	1	1	1	1	1	1	1	1
4690	2	3	2	2	2	3	2	3	2
4736	4	3	3	3	2	3	4	4	2
6245	2	1	1	1	1	1	1	1	1
7239	4	1	1	1	1	3	1	1	2
8907	1	2	1	1	1	1	1	2	1
9502	4	3	3	1	1	2	3	3	1
10359	4	2	2	2	2	1	2	2	1
12388	4	2	1	1	1	1	2	4	1
15339	4	3	2	3	1	1	2	2	1
15676	4	2	2	1	1	3	4	4	2
15718	4	2	1	1	1	1	4	1	1

16218	4	3	3	2	2	2	2	3	2
16419	4	2	1	1	1	3	4	2	1
16991	2	2	2	2	1	1	2	1	1
17266	1	2	1	1	1	1	1	1	1
17317	2	1	1	2	1	2	1	4	1
18155	4	2	1	1	1	2	1	1	1
19535	4	3	2	2	1	1	4	4	1
19538	4	3	2	2	2	2	4	4	1
19600	4	1	1	1	1	2	1	1	1
19775	2	2	2	1	1	1	1	1	1
19995	2	2	2	2	2	2	2	2	1

Jordan DeSantis Clinical Supervisor Theresa Johnson

Quality Assurance Manager