



Clinical Evaluation Report

ETC Panel No. 23076

ETC Entry No. 50474

CLINICAL EVALUATION REPORT

A One-Day Evaluation of LipSense® Cream

Long-wear, low-transfer, and brief water-exposure performance of a lip color.

SPONSOR	TEST FACILITY
SeneGence International, Inc.	Essex Testing Clinic (ETC) - Verona, New Jersey, USA
DESIGN	POPULATION
1-day, single-arm clinical use study with long-wear, transfer-proof and water-proof evaluations	32 female subjects, ages 19-50, enrolled and completed
CONDUCTED UNDER	EVALUATION POINTS
Good Clinical Practice, informed consent and ETC Standard Operating Procedures	Baseline; 4, 6 and 8 hours; after rubbing; and after 30-second water exposure

Tested product. LipSense Cream - identified in the signed Essex source as **LipSense Hydra Matte Lip Color**.



Conducted by **Essex Testing Clinic (ETC)**, an independent claim-substantiation laboratory. Final report dated April 4, 2023.



In a 1-day study of 32 women, Essex evaluated LipSense Cream under the source name LipSense Hydra Matte Lip Color. Mean appearance scores remained in the study's "good appearance" category at 4 hours: 3.2 by trained-technician assessment and 3.4 by participant assessment on a 0-to-4 scale.

The transfer assessment produced a mean transference score of 0.4 after rubbing, near the scale's "no evidence" category, although slight transference was observed. After 30 seconds of water exposure, all technician and subject mean appearance scores remained unchanged at 4.0 for both lips and forearm.

3.2 / 3.4

4-HOUR APPEARANCE

Technician / subject means; both in the "good" category.

0.4

TRANSFER SCORE

Mean after rubbing on a white towel; scale range 0-9.

4.0

AFTER WATER

All lip and forearm means remained "excellent."

1 OBJECTIVES & METHODS

1.1 Objectives

To determine the long-wear potential of the lip color at 4, 6 and 8 hours after application, and to evaluate its transfer-proof and water-proof potential under the study protocols.

1.2 Test article

- LipSense Cream, identified in the source report as LipSense Hydra Matte Lip Color
- Physical description: mauve cream

1.3 Use & assessments

- Applied to clean, dry lips and allowed to dry without pressing lips together
- Lip appearance scored by a trained technician and each subject on a 0-to-4 scale
- Transfer assessed by rubbing a white towel over a forearm test site
- Water exposure assessed on lips and a forearm test site for approximately 30 seconds

1.4 Claim criteria & analysis

The report used descriptive mean scores and prespecified category thresholds; it did not present statistical hypothesis testing. No control or comparator, randomization or blinding was reported. A long-wear or water-proof claim was considered supported when the applicable mean was in or near the "good appearance" category or above (2.5-4.0). A transfer-proof claim was considered supported when the mean was in or near the "slight transference" category (0-3).

Appearance scale: 4 = excellent; 3 = good; 2 = fair; 1 = poor; 0 = no product visible. Transfer scale: 0 = no evidence; 1-3 = slight; 4-6 = moderate; 7-9 = severe transference.

2 RESULTS - LONG-WEAR EVALUATION

Mean appearance scores on lips; higher score = better visible product appearance.

Timepoint	Technician mean	Subject mean	Study category
Baseline	4.0	4.0	Excellent
4 hours	3.2	3.4	Good
6 hours	1.9	2.3	Fair / near fair
8 hours	0.8	1.0	Poor / near poor

Interpretation. The 4-hour means remained above the prespecified 2.5 threshold, supporting a 4-hour long-wear claim. The 6- and 8-hour means were below that threshold.

3 RESULTS - TRANSFER & WATER EXPOSURE

3.1 Transfer evaluation

Approximately 5 minutes after application to a 2 cm by 2 cm forearm test site, a technician gently rubbed the site with a white towel and scored product transference.

Assessment	Mean score	Scale	Source-report observation
After rubbing	0.4	0-9	Slight transfer; mean near 0

Individual scores: 18 subjects scored 0 and 14 scored 1; no score exceeded 1. The source report concluded that the claim "transfer-proof" was supported under this forearm protocol.

3.2 Brief water-exposure evaluation

Five minutes after application, lips were splashed with water and forearms were submerged in 27 degrees C water, each for approximately 30 seconds.

Test site	Assessor	Baseline	After water	Change
Lips	Technician	4.0	4.0	0.0
Lips	Subjects	4.0	4.0	0.0
Forearm	Technician	4.0	4.0	0.0
Forearm	Subjects	4.0	4.0	0.0

Every mean remained in the "excellent appearance" category. The source report concluded that a "water-proof" claim was supported under these protocols.

4 CONCLUSION

Under the conditions of this 32-subject study, LipSense® Cream met the report's criterion for a 4-hour long-wear claim. The forearm assessment showed low transfer after rubbing, and appearance scores were unchanged after 30 seconds of water exposure on lips and forearm. In the signed source report, Essex Testing Clinic concluded that 4-hour long-wear, "transfer-proof," and "water-proof" claims were supported under those specified procedures.

Gabriela Argueta

Project Manager / Study Director
Essex Testing Clinic, Inc.

Toni F. Miller, PhD, DABT, BCFE

Scientific Director / Principal Investigator
Essex Testing Clinic, Inc.

Quality Assurance. The source report states that the study was conducted under Good Clinical Practice requirements, the Declaration of Helsinki and/or ETC Standard Operating Procedures, with informed consent obtained. ETC's Quality Assurance Unit audited the applicable records and report.

Independent source. ETC Panel No. 23076 / Entry No. 50474. The complete PDF includes the signed Essex report pages with study design, summary means, scoring thresholds, conclusions, signatures, and Quality Assurance documentation.

Notice. Results reflect the tested product and conditions; individual results may vary. This product is a cosmetic and is not intended to diagnose, treat, cure or prevent any condition. © SeneGence International.

INDEPENDENT LABORATORY SOURCE RECORD

Original Essex source pages follow.

These pages preserve the laboratory cover, signed investigator approvals, signed Quality Assurance statement, methods, complete aggregate findings, and conclusion for LipSense Hydra Matte Lip Color - now known as LipSense Cream.

LABORATORY Essex Testing Clinic, Inc.	PANEL / ENTRY 23076 / 50474
REPORT DATE 4 April 2023	PAGES REPRODUCED Source pages 1-11

Participant-identifying and participant-level scoring pages are not included. Aggregate findings, signatures, and Quality Assurance documentation are retained.



FINAL REPORT

CLINICAL EVALUATION OF THE WEAR PROPERTIES OF A LIPSTICK

LipSense Hydra Matte Lip Color

Sponsor

**SeneGence International
19651 Alter
Foothill Ranch, CA 92610**

Sponsor Representative

Nikki Chew

Clinical Testing Facility

**Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044**

**Sponsor Code: S174
ETC Panel No.: 23076
ETC Entry No.: 50474**

Date of Final Report

04-04-23

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SIGNATURE PAGE

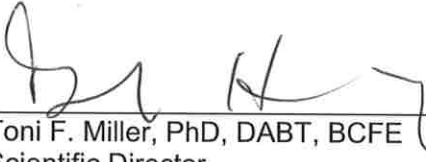
CLINICAL EVALUATION OF THE WEAR PROPERTIES OF A LIPSTICK

LipSense Hydra Matte Lip Color



Gabriela Argueta
Project Manager
Study Director

3/31/23
Date



Toni F. Miller, PhD, DABT, BCFE
Scientific Director
Principal Investigator

3/31/23
Date

QUALITY ASSURANCE STATEMENT

This study (ETC Panel No.: 23076; ETC Entry No.: 50474) was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in 21 CFR Part 50 (Protection of Human Subjects – Informed Consent) and the Standard Operating Procedures of Essex Testing Clinic, Inc.

For purposes of this clinical study:

- X Informed Consent was obtained.
- Informed Consent was not obtained.
- X An IRB review was not required.
- An IRB review was conducted and approval to conduct the proposed clinical research was granted.

To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the applicable study records and report. This report is considered a true and accurate reflection of the testing methods and source data.

Sherri L. Sayles
Sherri L. Sayles, MS
Manager, Quality Assurance

31 Mar 2023
Date

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CLINICAL EVALUATION OF THE WEAR PROPERTIES OF A LIPSTICK

LipSense Hydra Matte Lip Color

1.0 OBJECTIVES

The objectives of this study were to:

- determine the long-wear potential of the lipstick 4, 6, and 8 hours post-application;
- determine if the lipstick was transfer-proof; and
- determine the water-proof potential of the lipstick

on a panel of 30 female volunteers between 18-50 years old.

2.0 SPONSOR

SeneGence International
19651 Alter
Foothill Ranch, CA 92610

2.1 Sponsor Representative

Nikki Chew

3.0 CLINICAL INVESTIGATORS

Study Director: Gabriela Argueta
Project Manager

Principal Investigator: Toni F. Miller, PhD, DABT, BCFE
Scientific Director

4.0 CLINICAL TESTING FACILITY

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

5.0 STUDY DATE

Start/End: February 6, 2023

6.0 ETHICS

6.1 Ethical Conduct of the Study

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures (SOPs).

6.2 Subject Information and Consent

This study was conducted in compliance with 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. A copy of the Informed Consent was provided to each subject.

7.0 TEST ARTICLE

The test article used in this study was provided by:

SeneGence International
19651 Alter
Foothill Ranch, CA 92610

It was received on December 27, 2022 and identified as follows:

<u>ETC Entry No.</u>	<u>Qty Received</u>	<u>Test Article ID</u>	<u>Physical Description</u>
50474	35 Pieces	LipSense Hydra Matte Lip Color	Mauve cream

8.0 TEST SUBJECTS

A sufficient number of female subjects ranging in age from 18 to 50 years were to be empaneled so that 30 subjects would complete the study.

Each subject was to read, understand and sign a written Informed Consent Form and complete a brief Medical History Form.

9.0 STUDY DESIGN

9.1 Subject Selection

A sufficient number of female subjects, between 18 and 50 years of age and in general good health, were to be empaneled to ensure that approximately 30 completed the study. All subjects were required to read, understand and sign a written Informed Consent Form and complete a brief Medical History Form.

9.1.1 Inclusion Criteria

1. Females between the ages of 18 and 50 years, in general good health, who were able to read, understand and sign an Informed Consent Form.
2. Women who indicated their willingness to participate in the study, follow directions, and stay on the study for the entire duration.
3. Women who were free of any skin/lip condition or a history of skin/lip conditions that might have interfered with the purpose, conduct or integrity of the study.
4. Women who were regular users of lipstick.

9.1.2 Exclusion Criteria

1. Women who were pregnant, planning a pregnancy lactating and/or nursing a child.
2. Any woman who did not meet the inclusion criteria.
3. Women who had a known sensitivity to cosmetic products.
4. Women using systemic or topical anti-inflammatory agents with the exception of OTC acetaminophen (eg, Tylenol), ibuprofen (eg, Advil), or aspirin for 5 days prior to the start of testing.
5. Women who could not agree to not use systemic or topical anti-inflammatory agents, with the exception of OTC acetaminophen (eg, Tylenol), ibuprofen (eg, Advil) or aspirin during the course of the study.

9.0 STUDY DESIGN (CONT'D)

9.2 Test Procedure

The study was designed as a 1-day study (with long-wear, transfer-proof, and water-proof evaluations) in which the test article was used according to the Sponsor's use instructions: *Apply to clean, dry lips. Once applied, do not press lips together, let dry.*

9.2.1 Long-wear Evaluation

On the day of the study, subjects came to the Testing Facility wearing no cosmetics on their face/lips. Subjects applied the lipstick to their lips until the appearance score was a "4" according to the Sponsor's use instructions. Immediately post-application, the technician and subject scored the appearance of the product according to the following scale:

Test Site Appearance

- 4 = Excellent appearance
- 3 = Good appearance
- 2 = Fair appearance
- 1 = Poor appearance
- 0 = No product visible

Subjects returned to the Clinic 4, 6, and 8 hours post-application and scoring was repeated. Evaluations were based on a comparison of baseline versus the 4-, 6-, and 8-hour observation periods. If the mean score was in or near the "good appearance" category or above ("3" – 2.5 to 4.0) a long-wear claim was considered to be supported.

9.2.2 Transfer-proof Evaluation

After the 8 hour long-wear evaluation, subjects participated in the transfer-proof portion of the study. Subjects returned to the Testing Facility with "clean forearms" (free of any lotions or creams). A trained technician marked one 2 cm x 2 cm test site on the forearm of each subject then applied the test product to the subject's forearm until an excellent appearance was achieved. In order to determine the "transfer-proof" potential of the test product, approximately 5 minutes after application, the technician gently rubbed the subject's forearm with a white towel and scored the appearance of product transference (if any) on the towel according to the following scale:

Scale for Scoring Transference

- 0 = No evidence of any transference
- 1-3 = Slight transference visible
- 4-6 = Moderate transference visible
- 7-9 = Severe transference visible

If the mean score was in or near the "slight transference visible" category ("0-3" – 0 to 3.0) a transfer-proof claim was considered to be supported.

9.0 STUDY DESIGN (CONT'D)

9.2 Test Procedure (Cont'd)

9.2.3 Water-proof Evaluation

After the transfer-proof evaluation, subjects participated in the water-proof evaluation of the study. The trained technician marked one (1) 2 cm x 2 cm test site on the subject's forearm then applied the test product to the subject's forearm until an excellent appearance was achieved. Immediately after application, the technician and subject evaluated the appearance of the lipstick on the forearm.

Under the supervision of a trained technician, subjects applied the lipstick to their lips according to the Sponsor's use instructions until an appearance score of "4" was achieved. Immediately after application, the technician and subject evaluated the appearance of the lipstick on the lips.

Five (5) minutes after application to the lips, subjects splashed water on their lips for approximately 30 seconds. The technician and subject then scored the appearance of the lipstick. Five (5) minutes after application to the forearm, the subject submerged their forearm under water (27°C) for approximately 30 seconds and the evaluations were repeated.

Evaluations were conducted according to the scale outlined below:

Test Site Appearance – Lips:

4 = Excellent appearance
3 = Good appearance
2 = Fair appearance
1 = Poor appearance
0 = No product visible

Test Site Appearance – Forearm:

4 = Excellent appearance
3 = Good appearance
2 = Fair appearance
1 = Poor appearance
0 = No product visible

Evaluations were based on a comparison of baseline versus after water exposure. If the mean score was in or near the "good appearance" category or above ("3" – 2.5 to 4.0) a water-proof claim was considered to be supported.

10.0 RESULTS AND DISCUSSION

A total of 32 female subjects between the ages of 19 and 50 years were enrolled onto the study and completed on January 13, 2023. Subject demographics are presented in Appendix 1.

10.1 Long-wear Evaluation

Immediately post-application (baseline) and 4, 6, and 8 hours post-application, a trained technician and the subjects evaluated the appearance of the lipstick on the lips. Individual scores are presented in Appendix 2.

The following table presents a summary of mean appearance scores.

10.0 RESULTS AND DISCUSSION (CONT'D)

10.1 Long-wear Evaluation (Cont'd)

Long-wear Evaluation Mean Appearance Scores		
	Mean Score	
	Technician	Subjects
Baseline	4.0	4.0
4 Hours	3.2	3.4
6 Hours	1.9	2.3
8 Hours	0.8	1.0

When mean scores at baseline (immediately post-application) were compared with those at 4, 6, and 8 hours after application, there was a decrease in the appearance of the lipstick observed by the technician and subjects at all time points. However, mean scores were in the "good appearance" category ("3") at 4 hours, in or near the "fair appearance" category ("2") at 6 hours, and in or near the "poor appearance" category ("1") at 8 hours for both the technician and subject evaluations.

10.2 Transfer-proof Evaluation

Approximately 5 minutes after application, the technician rubbed the forearm of each subject with a white towel and graded the appearance of product transference (if any) on the towel. Individual scores are presented in Appendix 3.

The following table presents a summary of the transference evaluation.

Transfer-Proof Evaluation Mean Scores	
	Mean Score
After Rubbing	0.4

There was slight transference of the test product observed by the technician. The mean score remained near the "no evidence of any transference" category ("0") after rubbing.

10.3 Water-proof Evaluation

Test Site Appearance – Lips

Both the trained technician and the subjects evaluated the appearance of the lipstick on the lips before and after water exposure. Individual scores are presented in Appendix 4, Table 1.

The following table presents a summary of mean appearance scores.

Lip Evaluation Mean Appearance Scores				
Mean Score	Technician Evaluation		Subject Evaluation	
	Baseline	After Water Exposure	Baseline	After Water Exposure
	4.0	4.0	4.0	4.0

10.0 RESULTS AND DISCUSSION (CONT'D)

10.3 Water-proof Evaluation (Cont'd)

When compared with baseline (before splashing), there was no change in the appearance of the test product observed by either the trained technician or subjects (mean score of 4.0 vs 4.0) after the lips were splashed with water. The mean scores remained in the "excellent appearance" category ("4") for both the trained technician and subject evaluations.

Test Site Appearance – Forearm

The trained technician and the subjects evaluated the appearance of the product on the forearm before and after water exposure. Individual scores are presented in Appendix 4, Table 2.

The following table presents a summary of mean appearance scores.

Forearm Evaluation Mean Appearance Scores				
Mean Score	Technician Evaluation		Subject Evaluation	
	Baseline	After Water Exposure	Baseline	After Water Exposure
	4.0	4.0	4.0	4.0

When compared with baseline (before submersion), there was no change in the appearance of the test product observed by either the trained technician or subjects (mean score of 4.0 vs. 4.0) after the forearm was submerged in water for 30 seconds. Both mean scores remained in the "excellent appearance" category ("4") for both the trained technician and subject evaluations.

11.0 CONCLUSIONS

A 1-day long-wear, transfer-proof, and water-proof study of Test Article: **LipSense Hydra Matte Lip Color** was conducted with 32 female subjects.

Long-wear evaluations were conducted by a trained technician and the subjects immediately post-application of the test product and 4, 6, and 8 hours after product application. When mean scores at baseline were compared with those at 4, 6, and 8 hours, there was a decrease in the appearance of the lipstick observed by the technician and subjects at all time points. However, mean scores were in the "good appearance" category ("3") at 4 hours for both the technician and subject evaluations. A 4-hour "long-wear" claim is considered to be supported.

There was slight transference of the product observed after rubbing. Based on the results of the study, the claim "transfer-proof" is considered to be supported.

There was no change observed by the technician or subjects in the appearance of the lipstick on the lips and forearm after exposure to water. Mean scores remained in the "excellent appearance" category ("4") for both the trained technician and subject evaluations in the appearance of the lipstick on the lips and forearm. A "water-proof" claim is considered to be supported.