

SENEGENCE® EYECRÈME

Greater radiance and improved-looking crow's feet by Week 8.

Independent expert grading documented progressive improvement in eye-area radiance and crow's-feet appearance, supported by strong participant perceptions of brighter, smoother, more rested-looking eyes.



31 completed

8 weeks

Expert grading + participant perception

Tested as SGF19112-03

20.21%

improvement in eye-area radiance

WEEK 8

Expert grading, n=31; p<0.001.

87.10%

of participants improved in radiance

WEEK 8

Expert grading, n=31.

83.87%

said lines and wrinkles looked diminished

WEEK 8

Participant perception, n=31.

VISIBLE EYE-AREA RESULTS

Versus baseline, expert-graded radiance improved 14.51% at Week 6 and 20.21% at Week 8.

Radiance - expert-graded mean improvement 20.21%



Week 8, n=31; p<0.001.

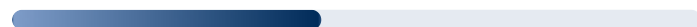
80.65%

said the eye area looked more rested.

77.42%

said the eye area looked brighter.

Crow's-feet appearance - expert-graded mean improvement 9.15%



Week 8, n=31; p<0.001.

77.42%

said the eye area looked smoother.

77.42%

said the eye area looked more awake.

Participants who improved in radiance 87.10%



Week 8, n=31.

TWO COMPLEMENTARY LENSES

Expert grades quantify visible appearance; participant percentages report self-perception. These results are presented separately so each claim keeps its proper evidence source.

TECHNICAL STUDY RECORD

The strongest substantiation is expert-graded visible appearance.

INDEPENDENT LABORATORY Validated Claim Support, LLC	STUDY / REPORT CS211048 / RE211048.V02
TESTED ARTICLE EyeCrème SA221009 / SGF19112-03	DESIGN 8-week single-arm baseline comparison
POPULATION 32 enrolled; 31 completed; ages 48-70	VISITS Baseline, immediate, Week 6, Week 8
EVIDENCE Expert grading, Corneometer, Glossometer, Visioscan, photography, questionnaire	SOURCE DATE 13 July 2022

Expert-graded appearance (n=31)

Expert endpoint	Week 6	Week 8
Radiance	14.51% improvement; 67.74% improved; p<0.001	20.21% improvement; 87.10% improved; p<0.001
Crow's-feet appearance	5.49% improvement; 29.03% improved; p=0.001	9.15% improvement; 41.94% improved; p<0.001

Lower grades indicate improvement.

Scope of instrumental support

Instrument endpoint	Finding	Interpretation
Corneometer hydration	Immediate -9.11%; p=0.049; Week 6 -5.98%; p=0.248; Week 8 -1.71%; p=0.734	Did not substantiate improved hydration
Glossometer shine	Immediate -29.62%; p<0.001	Did not substantiate increased shine
Visioscan SEw wrinkles	Week 6 +7.63%; p=0.452; Week 8 -2.92%; p=0.741	Week 8 favorable direction; not statistically significant

The report therefore leads with expert-graded radiance and crow's-feet appearance, not instrument hydration, shine, or wrinkle claims.

STUDY APPLICATION

Thirty-one participants completed the study. Results apply to EyeCrème SA221009 / SGF19112-03 under the reported eight-week study design.



INDEPENDENT LABORATORY EVIDENCE

Original source pages follow.

Selected original VCS pages follow, preserving the signed study summary, methods, aggregate results, conclusion, and Quality Assurance record while excluding participant-level material.

LABORATORY Validated Claim Support, LLC	STUDY / REPORT CS211048 / RE211048.V02
SOURCE DATE 13 July 2022	AUTHENTICATION Digital investigator + QA signatures

SOURCE AUTHENTICATION

The final report contains dated digital Quality Assurance and Principal Investigator signatures dated 13 July 2022.

Independent laboratory source pages are included in the complete PDF. Participant-identifying information has been removed where indicated; aggregate findings are unchanged.

Clinical Study Summary

Title	An 8 Week Study to Evaluate the Efficacy of an Eye Cream			
Clinical Study Number	CS211048			
Protocol	PR211048.V01			
Sponsor	SeneGence			
Study Design	Monadic			
Objectives	1. To assess the efficacy of a topical product to improve eye area hydration. 2. To assess the efficacy of a topical product to improve eye area radiance/shine. 3. To assess the efficacy of a topical product to improve the appearance of crow's feet. 4. To assess the efficacy of a topical product to improve the appearance of dark circles.			
Number of Subjects	30 to complete (31 completed)			
Target Population	Female subjects, age 30-70 years, open to all races and ethnicities			
Duration	8 Weeks [Baseline, Immediate, Week 6, Week 8]			
Test Product	SA Number	Name	Formula	Designation
	SA221009	EyeCrème	SGF19112-03	Eye Cream
Methods	Parameter	Assessment		
	Skin Hydration	• Corneometer • Subjective Questionnaire		
	Skin Shine, Radiance	• Glossometer • Expert Grading • Subjective Questionnaire		
	Crow's Feet	• Visioscan • Expert Grading • Subjective Questionnaire • Validated Clinical Photography (Subset of 8, with Analysis)		
	Dark Circles	• Subjective Questionnaire • Validated Clinical Photography (Subset of 8, with Analysis)		
Statistical Methodology	Data Type		Methods	
	Demographics		Descriptive Statistics	
	Instrumental Assessments & Expert Grading		Descriptive Statistics Paired T-Test (Baseline vs. Subsequent)	
	Subjective Questionnaire		Descriptive Statistics	
Study Schedule	Initiation	Baseline/Immediate	17 Feb 2022	
		Week 6	31 Mar 2022	
	Completion	Week 8	14 Apr 2022	

Summary	This study was an 8 Week efficacy evaluation of one test product. A panel of 31 subjects completed the study. In conclusion, under the conditions of this study, use of EyeCrème SGF19112-03 per Sponsor instructions, led to statistically significant improvements in the appearance of Radiance and Crow's Feet in the eye area after six and eight weeks, as revealed by results from Expert Grading. Directional improvements were noted in the Visioscan instrumental assessment at week 8. Subjective Questionnaire results showed an overall positive perception of the effects of the product. See Section 19.0 Results for further details.
----------------	---

Quality Assurance Statement

The Quality Assurance and Quality Control Department (QA/QC) at Validated Claim Support, LLC is independent of the employees involved in the investigation. The QA/QC unit is responsible for overseeing essential study documentation and, if requested by a Sponsor, monitoring study conduct. This statement confirms that the study was conducted in accordance with Good Clinical Practices and other applicable laws and regulations, as well as VCS Standard Operating Procedures and approved study protocol (where applicable). The Quality Department ensures this report accurately reflects data collected during the study.

Quality Assurance:

771A126C3E3
Stephanie Van Hollemeersch
ZorroSign

Signature & Date:

07/13/2022

Principal Investigator:

771A126C3CF
Anna Hardy
ZorroSign

Signature & Date:

07/13/2022



Table of Contents

1. Introduction	6
2. Objectives.....	6
3. Study Design.....	6
4. Test Product	6
5. Population	7
6. Methods.....	8
7. Procedure.....	8
8. Prohibitions & Restrictions for the Duration of the Study	9
9. Adverse Events	9
10. Indemnity Provision	9
11. Investigational Review Board (IRB).....	9
12. Informed Consent.....	10
13. Discontinuation	10
14. Changes to Protocol.....	10
15. Monitoring	11
16. Recording of Data	11
17. Safety & Ethics.....	11
18. Statistical Methods	11
19. Results.....	12
20. Conclusion.....	16

1. Introduction

This document is a report for a human research study. This study was conducted according to Validated Claim Support's approved study protocol (PR211048.V01), research policies, and Standard Operating Procedures, U.S., and international standards of Good Clinical Practice (FDA and ICH guidelines) and applicable government regulations.

2. Objectives

Data was analyzed with specific regard to the following objectives:

1. Improve eye area hydration, as demonstrated by Corneometer readings and Subjective Questionnaire results.
2. Improve eye area shine/radiance, as demonstrated by Glossymeter readings, Expert Grading, and Subjective Questionnaire results.
3. Improve the appearance of crow's feet, as demonstrated by Visioscan readings, Expert Grading, Subjective Questionnaire results, and Clinical Photography (Subset 8, with analysis).
4. Improve the appearance of dark circles, as demonstrated by Subjective Questionnaire results and Clinical Photography (Subset 8, with analysis).

3. Study Design

This was an eight-week study of the performance of one test product. The test product was used by each subject per Sponsor instructions. 31 subjects completed the study. Changes in skin condition was assessed by expert grading and instrumental assessments. Consumer perception of the product and its effects was determined from analysis of results from subjective questionnaires. Clinical Photography was conducted on a subset of 8 subjects and analysis was performed on the most improved parameter.

Evaluation points occurred at Baseline (BL), Immediately after first application and after six and eight weeks of use (W6, W8). A detailed outline of study visits appears in Section 7.0.

4. Test Product

Upon receipt of test samples at VCS, a unique code was assigned to the test product, and they were digitally logged into the system. Products were stored in a secure location and unused products will be discarded upon issue of the final report.

Sponsor purports that toxicology, microbiology, preservative efficacy, and/or other in-vitro/in-vivo safety and performance analyses were conducted as required by law or as recommended by legal counsel and that the test article does not contain antibiotics, antiseptics, steroids, hormones, or any other substances at levels of concentration requiring label declaration by the relevant regulatory authorities.

Sample No.	Name	Formula	Designation
Test Products			
SA221009	EyeCrème	SGF19112-03	Eye Cream

4.1 Use Instructions

Subjects were provided verbal and written use instructions, per protocol.

4.2 Onsite Product Application

Test product was applied on site per instructions listed in the protocol.

5. Population

5.1. Sample size

32 healthy subjects were enrolled into the study and 31 completed. One (1) subject discontinued. All subjects completed VCS required documentation, were assigned an MRN (Medical Record Number, a unique identification number), satisfied the study-specific inclusion and exclusion criteria and gave written informed consent.

5.2. Inclusion Criteria

1. Female subjects of any race, in good general health, aged 30-70 years old, inclusive at enrollment.
2. Individuals who were able to cooperate with the Principal Investigator and study personnel throughout the duration of the study and were willing to comply with all study procedures, methods, evaluations, and study product use.
3. Individuals who were able to read, understand, and willing to sign an informed consent for this specific study and have completed all VCS required documentation prior to study enrollment (Registration and Medical History).
4. Individuals who were willing to be photographed and sign a model release.
5. Individuals with mild to moderate crow's feet.
6. Individuals with mild to moderate dark circles.

5.3 Exclusion Criteria

1. Individuals with acute or chronic disease(s) or medical condition(s), including dermatological problems, which could put them at risk in the opinion of the Principal Investigator or compromise the study outcome. Typical uncontrolled chronic or serious diseases and conditions which would prevent participation in any clinical study are cancer, AIDS, insulin dependent diabetes, renal impairment, mental illness, and/or drug/alcohol addiction.

2. Individuals with a history of melanoma, or a treated skin cancer within the last 5 years.
3. Individuals who were pregnant, lactating, or planning to become pregnant. Individuals who become pregnant during the study must inform the Principal Investigator immediately.
4. Individuals who were unreliable or unlikely to be available for the duration of the study.
5. Individuals with a history of allergic reactions, skin sensitization and/or known allergies to cosmetic and personal care products/ingredients.
6. Individuals who were immunocompromised.
7. Individuals who were employees of VCS or other testing firms/laboratories, cosmetic or raw goods manufacturers or suppliers.
8. Individuals who were unable to communicate or cooperate with the Principal Investigator/study personnel due to language problems, poor mental development, or impaired cerebral function.
9. Individuals who had started Hormone Replacement Therapy within the last three months preceding the commencement of the study.
10. Individuals who were using oral contraception for less than three months before study commencement or who have changed their contraceptive method within the three months before the Baseline visit or planned to modify their contraception treatment within the duration of the study.
11. Individuals who had regular salon and/or dermatological procedures that can interfere with study results (Eyelash extensions, Eyebrow Microblading, Microdermabrasion, Fillers, Facial Peels, etc.) and were not willing to stop throughout the study. (Photo Subset Only)
12. Individuals who planned to change their hairstyle throughout the course of the study or who wear hair coverings regularly (i.e., wigs, coloring, extensions, etc.). (Photo Subset Only)
13. Individuals who had travelled (domestically or internationally) 10 days prior to any visit throughout the study. ***New Jersey travel guidelines will be referred to in order to determine requirements post-travel.***
14. Individuals with COVID-19 related symptoms, per CDC, within 10 days prior to any visit throughout the study.
15. Individuals who had used a fever/pain reducer within 24 hours prior to any site visit.

6. Methods

This study was performed in accordance with VCS final signed clinical study protocol (VCS.PR211048.V01) signed on 16 Feb 2022. A detailed description of study methods is outlined in the clinical study protocol referenced herein.

7. Procedure

This study included the following visits: Baseline, Week 6, and Week 8. A detailed description of procedures is outlined in the clinical study protocol referenced herein.

15. Monitoring

The study was not monitored by the Sponsor.

16. Recording of Data

All data and information, except electronically recorded data (all instrumentation and expert grading) is recorded on specific paper case report forms (CRFs) and this information is neatly recorded in type or legibly printed in black or blue ink wherever possible. Any errors were crossed with a single line and the correct entry was made and initialed and dated by the Principal Investigator or their designee, unless the CRF is also a source document completed by the subject (such as a questionnaire) in which case the correction(s) are made by the subject as described above.

17. Safety & Ethics

Regarding COVID-19, VCS followed all internal safety procedures to adhere to all federal and local requirements and regulations and implemented a number of additional recommendations to reduce the risk of transmission of this novel virus as described in VCS Standard Operating Procedure (SOP-017). The study was conducted in compliance with the main principles of Good Clinical Practice (GCP) under International Conference of Harmonisation (ICH) Harmonised Tripartite Guideline on GCP E6(2). The practices and procedures conducted during this study pertaining to informed consent, subject safety, investigator responsibility, and adverse event reporting were designed to comply with ICH E6. This study is not intended for submission to the FDA. The study conformed to the requirements of the Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013).

18. Statistical Methods

Statistical analysis was performed internally by VCS personnel per protocol. Data analysis is excluded for subjects who were discontinued from the study.

19. Results

Demographic Summary			
Variable		N	%
Sex	Female	31	100.00%
Race & Ethnicity	Black	2	6.45%
	Caucasian	29	93.55%
Age	Mean	59.65	
	Min	48	
	Max	70	

Corneometer Summary						
Time Point	n	Mean ± SD			p-value	Mean Percent Change from Baseline
Baseline	31	44.26	±	12.91		
Immediate	31	40.23	±	11.09	0.049**	-9.11%
Week 6	31	41.61	±	11.01	0.248	-5.98%
Week 8	31	43.50	±	11.92	0.734	-1.71%

Increase = Improvement

**Indicates a statistically significant worsening compared to baseline, $p \leq 0.050$

Corneometer: No improvements were observed.

Glossymeter Summary						
Time Point	n	Mean ± SD			p-value	Mean Percent Change from Baseline
Baseline	31	3.58	±	1.95		
Immediate	31	2.52	±	1.59	0.000*	-29.62%

Increase = Improvement

**Indicates a statistically significant worsening compared to baseline, $p \leq 0.050$

Glossymeter: No improvements were observed.

Expert Grading								
Assessment	Time Point	n	Mean $\pm$ SD			p-value	Mean Percent Change from Baseline	Percent of Subjects with Improvement
Radiance	Baseline	31	6.23	$\pm$	1.02			
	Week 6	31	5.32	$\pm$	0.98	0.000*	-14.51%	67.74%
	Week 8	31	4.97	$\pm$	0.98	0.000*	-20.21%	87.10%
Crow's Feet	Baseline	31	5.29	$\pm$	1.49			
	Week 6	31	5.00	$\pm$	1.39	0.001*	-5.49%	29.03%
	Week 8	31	4.81	$\pm$	1.40	0.000*	-9.15%	41.94%

Decrease = Improvement

*Statistically Significant (p<0.050)

Expert Grading: Statistically significant improvements from Baseline were seen in mean scores for Radiance and the appearance of Crow's Feet at Weeks 6 and 8.

Visioscan Summary								
SEw (Wrinkles)	Time Point	n	Mean $\pm$ SD			p-value	Mean Percent Change from Baseline	Percent of Subjects with Improvement
	Baseline	31	167.38	$\pm$	95.21			
	Week 6	31	180.15	$\pm$	76.93	0.452	7.63%	41.94%
	Week 8	31	162.49	$\pm$	86.69	0.741	-2.92%	64.52%

Decrease = Improvement

*Statistically Significant (p<0.050)

Visioscan (SEw): Directional improvements from Baseline mean scores were observed for SEw (wrinkles) at Week 8.

SEw is calculated from the average number and average width of horizontal and vertical wrinkles (calculatory lines). The **more visible wrinkles (broad, deep wrinkles)** the **higher** this value.

Questionnaire Summary Week 6 (n=31)							
No.	Question	Completely Agree	Slightly Agree	Neither Agree or Disagree	Slightly Disagree	Completely Disagree	Favorable Response (≥50% of Panel)
1	My eye area looks brighter	8 (25.81%)	12 (38.71%)	8 (25.81%)	2 (6.45%)	1 (3.23%)	64.52%
2	My eye area looks more radiant	7 (22.58%)	12 (38.71%)	9 (29.03%)	0 (0.00%)	3 (9.68%)	61.29%
3	My under-eye puffiness looks reduced	10 (32.26%)	8 (25.81%)	9 (29.03%)	1 (3.23%)	3 (9.68%)	58.06%
4	My eye area looks more rested	9 (29.03%)	9 (29.03%)	10 (32.26%)	1 (3.23%)	2 (6.45%)	58.06%
5	My eye area looks younger	9 (29.03%)	10 (32.26%)	8 (25.81%)	2 (6.45%)	2 (6.45%)	61.29%
6	My dark circles look diminished	4 (12.90%)	10 (32.26%)	15 (48.39%)	1 (3.23%)	1 (3.23%)	45.16%
7	The skin around my eyes immediately felt hydrated	17 (54.84%)	12 (38.71%)	0 (0.00%)	1 (3.23%)	1 (3.23%)	93.55%
8	My eye area looks refreshed	9 (29.03%)	12 (38.71%)	7 (22.58%)	1 (3.23%)	2 (6.45%)	67.74%
9	My eye area looks nourished	13 (41.94%)	8 (25.81%)	7 (22.58%)	1 (3.23%)	2 (6.45%)	67.74%
10	My eye area looks more luminous	7 (22.58%)	9 (29.03%)	11 (35.48%)	2 (6.45%)	2 (6.45%)	51.61%
11	My eye area looks more awake	8 (25.81%)	10 (32.26%)	9 (29.03%)	2 (6.45%)	2 (6.45%)	58.06%
12	My eye area looks less crepey	10 (32.26%)	7 (22.58%)	11 (35.48%)	1 (3.23%)	2 (6.45%)	54.84%
13*	My crow's feet look reduced	12 (40.00%)	7 (23.33%)	8 (26.67%)	1 (3.33%)	2 (6.67%)	63.33%
14	My lines and wrinkles appear diminished in just 6 weeks	8 (25.81%)	11 (35.48%)	9 (29.03%)	0 (0.00%)	3 (9.68%)	61.29%
15	My eye area looks smoother	11 (35.48%)	12 (38.71%)	5 (16.13%)	0 (0.00%)	3 (9.68%)	74.19%

*Missing response, n=30

At Week 6, the majority of subjects (>50% of the panel) responded favorably to 14 out of 15 statements regarding the condition and appearance of their skin.

Questionnaire Summary Week 8 (n=31)							
No.	Question	Completely Agree	Slightly Agree	Neither Agree or Disagree	Slightly Disagree	Completely Disagree	Favorable Response (≥50% of Panel)
1	My eye area looks brighter	11 (35.48%)	13 (41.94%)	5 (16.13%)	1 (3.23%)	1 (3.23%)	77.42%
2	My eye area looks more radiant	9 (29.03%)	14 (45.16%)	6 (19.35%)	1 (3.23%)	1 (3.23%)	74.19%
3	My under-eye puffiness looks reduced	13 (41.94%)	9 (29.03%)	5 (16.13%)	1 (3.23%)	3 (9.68%)	70.97%
4	My eye area looks more rested	10 (32.26%)	15 (48.39%)	3 (9.68%)	1 (3.23%)	2 (6.45%)	80.65%
5	My eye area looks younger	7 (22.58%)	14 (45.16%)	8 (25.81%)	1 (3.23%)	1 (3.23%)	67.74%
6	My dark circles look diminished	5 (16.13%)	15 (48.39%)	8 (25.81%)	1 (3.23%)	2 (6.45%)	64.52%
7	The skin around my eyes immediately felt hydrated	11 (35.48%)	10 (32.26%)	7 (22.58%)	2 (6.45%)	1 (3.23%)	67.74%
8	My eye area looks refreshed	14 (45.16%)	8 (25.81%)	7 (22.58%)	1 (3.23%)	1 (3.23%)	70.97%
9	My eye area looks nourished	13 (41.94%)	7 (22.58%)	9 (29.03%)	1 (3.23%)	1 (3.23%)	64.52%
10	My eye area looks more luminous	10 (32.26%)	10 (32.26%)	9 (29.03%)	1 (3.23%)	1 (3.23%)	64.52%
11	My eye area looks more awake	11 (35.48%)	13 (41.94%)	6 (19.35%)	0 (0.00%)	1 (3.23%)	77.42%
12	My eye area looks less crepey	11 (35.48%)	11 (35.48%)	8 (25.81%)	0 (0.00%)	1 (3.23%)	70.97%
13*	My crow's feet look reduced	10 (32.26%)	10 (32.26%)	10 (32.26%)	0 (0.00%)	1 (3.23%)	64.52%
14	My lines and wrinkles appear diminished in just 6 weeks	12 (38.71%)	14 (45.16%)	3 (9.68%)	1 (3.23%)	1 (3.23%)	83.87%
15	My eye area looks smoother	11 (35.48%)	13 (41.94%)	5 (16.13%)	1 (3.23%)	1 (3.23%)	77.42%

At Week 8, the majority of subjects (>50% of the panel) responded favorably to all 15 statements regarding the condition and appearance of their skin.

20. Conclusion

In conclusion, under the conditions of this study, use of **EyeCrème SGF19112-03** per Sponsor instructions, led to statistically significant improvements in the appearance of Radiance and Crow's Feet in the eye area after six and eight weeks, as revealed by results from Expert Grading. Directional improvements were noted in the Visioscan instrumental assessment at week 8. Subjective Questionnaire results showed an overall positive perception of the effects of the product.