

EFFICACY TEST REPORT

LIP CARE FLAVOUR FREE

OVERVIEW

Beesline laboratories have been developing a highly effective natural lip care that soothes, moisturizes and regenerates dry and chapped lips. There is a supposition that this formula gives fast relief for lips: regeneration of youthful and healthy appearance after 2 days application or more less.

TEST OBJECTIVE

This study aimed to evaluate the efficacy of the lip care in improving the condition and the hydration state of the lips.

- By visual assessment of lip parameters of the lower lip by investigator: Lip cracking/fissuring, fine lip lines due to dryness, overall condition, lip color/rosiness, lip definition/contour, and lip texture/visual roughness, using a 10cm analog scale at each clinic visit.
- By taking standardized digital photographs of the lips in a relaxed, closed position at each time point.
- By subject self-assessment questionnaire asking them to rate their experience using the lip products within minutes of initial application and at each time point.

STUDY DESIGN

Table 1. Study design.

NUMBER OF CENTER	BLINDNESS	NUMBER OF SAMPLES	STUDY DURATION	SEASON
Mono-/di- or multi- centric	Open label	One sample	1 week with visits at baseline, day2, day5, and day7	Autumn

SUBJECTS

Table 2. Selection criteria.

SELECTION CRITERIA

25 healthy man or women

Aged 18 to 55 years

Having both mild to moderate dryness of the lower lip as determined by:

- a clinical grader
- self-perceived

Being regular users of lip products (clear or colored) at least four times a week

Being non-smoker.

Willing to wear the test product for at least 8 hours per day, every day, for the duration of the study, with a minimum application of 3 times a day

Not having a history of lip injections or lip surgery.

Agreed not to apply any product (lipstick, lip gloss, lip conditioner, ...) to the lips other than the test product for the duration of the study.

Discontinue of using all lip-enhancement products a minimum of three days prior to the baseline visit.

Cooperative and available during the study period

Signed a voluntary informed consent and photography consent after the purpose of the study, the protocol, timetable, possible benefits, constraints linked to the study, and possible risks of the study were all explained

TEST MATERIALS

- One formula of fragrance free lip care will be tested.

TREATMENT

- Subjects will be instructed to wear the test product for at least 8 hours per day, every day, for the duration of the study, with a minimum application of 3 times a day
- Investigator will assess some lip parameters pre-application at baseline then he/she will take digital photography pre- and post-application at baseline and at each time point.
- Subjects will complete a self-assessment questionnaire at each time point without considering the application or not of the product on lips.
- All assessments will be performed after washing the face with water (or a facial cleanser) and acclimatization for 10 minutes in a room kept at $22 \pm 2^\circ$ with $50 \pm 5\%$ relative humidity..

EVALUATION METHODS

Table 3. Type of evaluation methods.

VISUAL ASSESSMENT	DIGITAL PHOTOGRAPH	SELF-ASSESSMENT
<p>It is a visual assessment for the following parameters* by investigator using a 10cm analog scale at each clinic visit:</p> <ol style="list-style-type: none">1- Overall condition2- Lip cracking/fissuring3- Fine lip lines due to dryness4- Lip definition/contour5- Lip color/rosiness6- Lip texture/visual roughness <p>*Assessment with no product on the lips.</p>	<p>Standardized digital photographs will be taken at baseline (pre-and post-application*), and at each time point: day 2, day 5 and day7 (pre- and post-application). Pre-application: no product on the lip Post-application: with product on the lip Then image analysis will be conducted to re-assess the following parameters using a 10cm scale:</p> <ol style="list-style-type: none">1- Overall condition2- Lip cracking/fissuring3- Fine lip lines due to dryness4- Lip definition/contour <p>Digital Photograph post-application at baseline help to study the instant effects.</p>	<p>Subjects will assess the following parameters using a 1-5 scale:</p> <p>(a) Improvement:</p> <ol style="list-style-type: none">1- Improved overall lip condition2- Helped prevent lip dryness3- Improved lip outline/contour4- Enhanced color5- Improved lip appearance6- Made lips feel smoother/softer7- Lips look and feel healthier <p>(b) Usefulness:</p> <ol style="list-style-type: none">8- Is good for everyday use9- Not oily or greasy10- Would use if available <p>The 1-5 score scale is:</p> <ol style="list-style-type: none">1. Strongly Agree (= Markedly improved/Very useful)2. Agree (= Improved/Useful)3. Slightly agree (Slightly improved/Slightly useful)4. Disagree (Unchanged/Useless)5. Strongly disagree (Aggravated/Harmful) <p>This assessment reflects the presence or absence of statistically significant improvements and of product acceptance according to subjects' perception.</p>

*During Subject recruitment: investigate from which discomfort subjects with dry lips could usually complain (that could help market the results of this assessment).

SCORESHEETS FOR MEASUREMENTS

See "Score sheet Efficacy Lip Care" Excel sheet.

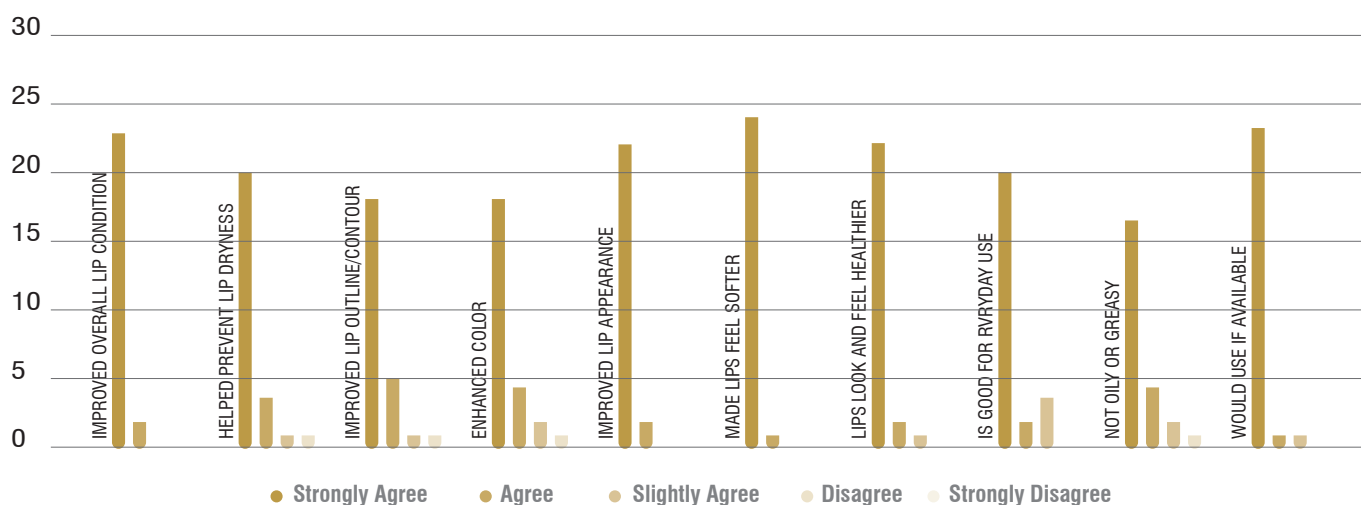
STATISTICAL ANALYSIS

ASSESSMENT TIME POINTS

TIME POINT	TYPE OF EVALUATION
Baseline, T0	Visual Assessment Digital Photograph
Day 2, T1	Visual Assessment Digital Photograph Self-assessment
Day 5, T2	Visual Assessment Digital Photograph Self-assessment
Day 7, T3	Visual Assessment Digital Photograph Self-assessment



SELF-ASSESSMENT RESULTS AFTER DAY 7



REFERENCES

2009. Trookman NS, Rizer RL, Ford R, Mehta R, Gotz V. Clinical assessment of a combination lip treatment to restore moisturization and fullness.
2017. Makino ET, Tan P, Qian K, Babcock M, Mehta RC. Clinical Assessment of Immediate and Long-Term Effects of a Two-Step Topical Hyaluronic Acid Lip Treatment.
2017. Isoda K, Nakamura T, Yoshida K, Tamura E, Atsuta N, Ishida K, Takagi Y, Mizutani H. The efficacy of a lip balm containing pseudo-ceramide on the dry lips of sensitive skin-conscious subjects.