Interventional Results Summary

Study Number: 218006
Title: A Clinical Study to Evaluate the 8-Hour Moisturization Efficacy of an Over-The-Counter Sunscreen Lip Balm After a Single Application
Sponsor: Haleon
Study Center: The study was conducted at single center in United States.
Actual First Subject First Visit: 07 Dec 2021
Actual Last Subject Last Visit: 17 Dec 2021
Product / Medicine: ChapStick Active Performance Unscented
Brief Summary: The purpose of this study was to evaluate the 8-hour moisturization efficacy of OTC sunscreen lip balm after a single treatment application.
Phase: Not Applicable
Study Design: A single-center, randomized, controlled, intra-individual comparison, open label clinical study to determine the 8-hour moisturization efficacy of a sunscreen lip balm. Skin hydration assessed before (Baseline) and after (2, 4, 6 and 8 hours post-treatment) a single treatment with test product, compared to 'no treatment' as control, using a corneometer. Study treatments was randomly assigned to 2 test sites delineated on the skin of the participant's volar forearms (one test site on each arm). A 1-week conditioning phase preceded the test day, during which participants used a standard soap provided for personal washing.
Actual Enrolment: 39
Study Population: • Participant had provided a signed and dated, legally effective, informed consent document, which indicated they had been informed of, and understand, all pertinent aspects of the study, before any study procedures were performed (in conformance with 21 Code of Federal Regulations [CFR] Part 50: 'Protection of Human Subjects.') • Participant provided relevant details of their medical history and current/recent medications and treatments. • Participant had completed a Health Insurance Portability and Accountability Act (HIPAA) Authorization Form in conformance with 45 CFR Parts 160 and 164. • Participant completed a Photo Release Form. • Participant was able to read, write, speak and understand English. • Participant had good general health. • Participant had a valid form of personal identification (photo identity [ID], driver's license, passport, permanent resident card, military ID card; forms cannot be expired) • Male and female participants of child-bearing potential agreed to use a highly effective method of contraception for the duration of the study and for 14 days after treatment application. (Note: A participant was considered to be of child-bearing potential if, in the opinion of the Principle investigator [PI], they were biologically capable of having children and sexually active). • Participant agreed to be sequestered in a temperature/humidity monitored test room at the clinical site (temperature 21 degree Celsius [C] plus minus [+/-] 2 degree C, relative humidity [RH] 50 percent [%] +/- 10%) for the duration of the test day (Visit 2), approximately 9.5 hours. • Participant agreed to bring their own food (dry) and beverages to consume on the test day (Visit 2).

- Participant agreed not to consume hot or very cold food/beverages on the test day (Visit 2).
- Participant agreed to use the non-moisturizing soap provided for all personal washing during the conditioning phase of the study.
- Participant agreed to wear loose clothing for ease of access to the test sites (arms) and/or sleeves that could be easily rolled up.
- Participant agreed not to introduce any new cosmetic/toiletry products into their personal care regimen during the study.
- Participant agreed to refrain from any physical effort which might result in thermal regulation by sweating (for example, exercise class, rapid climbing of flights of stairs, jogging, cycling, brisk walking) for at least 2 hours prior to arriving the test day (Visit 2).
- Participant agreed to refrain from prolonged or excessive ultraviolet (UV) exposure (for example, sunbathing, tanning beds) for the duration of the study.
- Participant was dependable and able to follow directions as outlined in the protocol and Informed Consent Form (ICF).

Study Investigators/Centers:
GSK Investigational Site; Piscataway, New Jersey, United States, 08854

Indication(s): Sunscreening Agents

Study Outcomes:

Primary Outcomes:

1. Mean Change From Baseline in Corneometer Measurements
   [Time Frame: Baseline (pre-treatment), 2, 4, 6 and 8 hours post-treatment]

Secondary Outcomes:

2. Percentage of Participants With Improved Corneometer Measurement
   [Time Frame: 2, 4, 6 and 8 hours post-treatment]

Study Results:

Arm/Group Title	All Study Participants
Period Title: Overall Study	
Started	38
Safety Population	37
Test Product (CAP UnScented)	36
Control (No Treatment)	36
Completed	36
Not Completed	2
Reason Not Completed	
Lost to Follow-up	1
Discontinued for non-compliance	1

Baseline Characteristics:

Arm/Group Title	All Study Participants
Overall Number of Baseline Participants	37
Baseline Analysis Population Description:	Safety population: included all randomized participants who received study treatment.

Age, Continuous Mean (Standard Deviation) Unit of measure: Years		55.6 (12.3)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Female Male	25 (67.57%) 12 (32.43%)
Race/Ethnicity, Measure Type: Count of Participants Unit of measure: participants	Number Analyzed Comment:	0 Measure Analysis Population Description: Race and Ethnicity were not collected from any participant.
Primary Outcome Results: **1. Mean Change From Baseline in Corneometer Measurements** [Time Frame: Baseline (pre-treatment), 2, 4, 6 and 8 hours post-treatment]		
Analysis Population Description: Primary analysis population: included all eligible participants who were randomized, received study treatment and provided at least one post-treatment efficacy assessment.		
Arm/Group Title	Test Product	Control (No Treatment)
Overall Number of Participants Analyzed	36	36
Mean (Standard Deviation) Unit of Measure: Corneometry units		
Row Title		
Baseline	23.5 (5.7)	24.2 (6.0)
Change from Baseline 2 hours post-treatment	2.4 (4.2)	-0.6 (2.3)
Change from Baseline 4 hours post-treatment	1.7 (3.5)	-0.1 (2.7)
Change from Baseline 6 hours post-treatment	2.0 (5.3)	0.0 (2.6)
Change from Baseline 8 hours post-treatment	1.0 (3.3)	-0.2 (2.7)
Statistical Analysis 1		
Statistical Analysis Overview	Comparison Group	Test Product versus (Vs) Control (No Treatment)
	Comments	Pairwise comparison between Treated and Untreated sites 2 hours post-treatment
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	Less than (<) 0.0001
	Method	ANCOVA
	Comments	Analysis of Covariance (ANCOVA) model with treatment, timepoint, treatment*timepoint (interaction) and subject as terms; Baseline value as covariate.

Method of Estimation	Estimation Parameter	Other [Adjusted Mean Difference]
	Estimated Value	2.8
	95% Confidence Interval	1.7 to 3.9
Statistical Analysis 2		
Statistical Analysis Overview	Comparison Group	Test Product Vs Control (No Treatment)
	Comments	Pairwise comparison between Treated and Untreated sites 4 hours post-treatment
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.0077
	Method	ANCOVA
	Comments	ANCOVA model with treatment, timepoint, treatment*timepoint (interaction) and subject as terms; Baseline value as covariate.
Method of Estimation	Estimation Parameter	Other [Adjusted Mean Difference]
	Estimated Value	1.5
	95% Confidence Interval	0.4 to 2.7
Statistical Analysis 3		
Statistical Analysis Overview	Comparison Group	Test Product Vs Control (No Treatment)
	Comments	Pairwise comparison between Treated and Untreated sites 6 hours post-treatment
	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.0019
	Method	ANCOVA
	Comments	ANCOVA model with treatment, timepoint, treatment*timepoint (interaction) and subject as terms; Baseline value as covariate.
Method of Estimation	Estimation Parameter	Other [Adjusted Mean Difference]
	Estimated Value	1.8
	95% Confidence Interval	0.7 to 2.9
Statistical Analysis 4		
Statistical Analysis Overview	Comparison Group	Test Product Vs Control (No Treatment)
	Comments	Pairwise comparison between Treated and Untreated sites 8 hours post-treatment

	Type of Statistical Test	Superiority
Statistical Test of Hypothesis	P-Value	0.0707
	Method	ANCOVA
	Comments	ANCOVA model with treatment, timepoint, treatment*timepoint (interaction) and subject as terms; Baseline value as covariate.
Method of Estimation	Estimation Parameter	Other [Adjusted Mean Difference]
	Estimated Value	1.0
	95% Confidence Interval	-0.1 to 2.2
Secondary Outcome Results: **2. Percentage of Participants With Improved Corneometer Measurement** [Time Frame: 2, 4, 6 and 8 hours post-treatment]		
Analysis Population Description: Primary analysis population		
Arm/Group Title	Test Product	Control (No Treatment)
Overall Number of Participants Analyzed	36	36
Measure Type: Number Unit of Measure: Percentage of participant		
Row Title		
2 hours post-treatment	69.4	38.9
4 hours post-treatment	66.7	44.4
6 hours post-treatment	66.7	55.6
8 hours post-treatment	66.7	50.0
Adverse Events		
Time Frame	From screening until 14 days after last administration of study product (or last study procedure).	
Collection Approach for Table Default	Non-systematic Assessment	
All-Cause Mortality		
Arm/Group Title	All Study Participants	
	Affected / at Risk (%)	
Total	0/37 (0%)	
Serious Adverse Events		
Arm/Group Title	All Study Participants	
	Affected / at Risk (%)	
Total	0/37 (0%)	
Other (Not Including Serious) Adverse Events		
Frequency Threshold for Reporting Other Adverse Events	0%	
Arm/Group Title	All Study Participants	
	Affected / at Risk (%)	
Total	0/37 (0%)	
Limitations and Caveats: Not Applicable		