

Consumer Trial Report

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Study Details

Investigational Product	Dr V LipX Lip Care Kit
Client/Sponsor	Ace Medicine Ltd
Client Address	27 Old Gloucester Street, London, WC1N 3AX
Co-ordinator	-
Co-ordinator Address	-
Primary Contact	Vanita Rattan (info@acemedicine.com)
Client Formula Reference	-
Batch Reference	-
ADSL Reference	1470
Study Objective	The objective of the study is to assess the consumer opinion of Dr V LipX Lip Care Kit over a 6 month period amongst a panel of healthy subjects. The objective is to substantiate marketing claims.
Service Category	Consumer trial
Start / End Date	04.03.2020 - 31.08.2020
Duration	6 months
Published	22.09.2020

Subject Recruitment & Demographics

Gender	Female	Male	Total / Min / Max
Number of Subjects	24	-	24
Lowest Age	19	-	19
Highest Age	45	-	45

Additional Panellist Information

Female, Asians and Africans (Fitzpatrick group 5 or 6). Concerns include; Pigmentation issues (i.e. Hyperpigmentation), Naturally thin lips (proposed for fine tuning audience) Dry lips (proposed for fine tuning audience).

Study Methodology & Instructions

Usage Instructions

Evening skincare routine: 2 hours before bed in the early evening please do your lip kit routine so you get full penetration of the product without it coming off on your sheets. 3 nights a week GENTLY apply the Lip Scrub provided to take the top layer of dead skin cells away to allow active ingredients to penetrate. Apply 2 pumps of the Lip Mask to your finger then onto the lips. Leave this on for 30 mins as you continue your evening before washing it off and applying the Lip Balm provided to seal the actives into the skin. For the other 4 nights a week please apply your lip balm after your last meal. Skin cells have a slow turn around rate and results take a few months of being consistent. This is why compliance with the protocol is essential. The Lip mask and Lip balm will tingle then subside. You will need to apply SPF30 lip balm multiple times during the day.

Safety Warning for Panellists

If irritation occurs, discontinue use. Avoid contact with the eye area. If the product gets into your eyes, rinse well with cool water until irritation subsides.

Special Instructions & Notes

Product Name

Dr V LipX Lip Care Kit

Formula Reference

-

Ingredients Listing (INCI)

GLYCERIN, BUTYLENE GLYCOL, AQUA, GLYCYRRHIZA GLABRA ROOT EXTRACT, ARCTOSTAPHYLOS UVA URSI LEAF EXTRACT, KOJIC DIPALMITATE, CITRUS UNSHIU PEEL EXTRACT, PHENOXYETHANOL, ALPHA-ARBUTIN, BUTYROSPERMUM PARKII BUTTER, CAPRYLIC/CAPRIC TRIGLYCERIDE, PARAFFINUM LIQUIDUM, Tocopheryl Acetate, SUCROSE, Jojoba Oil, POTASSIUM AZELOYL DIGLYCINATE, NIACINAMIDE, IMPERATA CYLINDRICA ROOT EXTRACT, POLYACRYLATE CROSSPOLYMER-6, PANTHENOL, METHYL PARABEN, PHYTIC ACID, OCTADECENEDIOIC ACID, PANTOLACTONE, GLYCERYL STEARATE, CETEARETH-20, CETEARETH-12, CETYL PALMITATE, CETEARYL ALCOHOL, ALCOHOL, SODIUM HYALURONATE, ACETYL GLUCOSAMINE, PEG-8, CARBOMER, LECITHIN

Summary of Data

Pre-assessment summary

Subject	Were you born with pinker lips?	Has your lip pigmentation darkened over time?	Have you previously tried to treat dark pigmentation on your lips?	Has anything worked?	Please briefly let us know what product or process previously worked.	Did a specific incident cause lip pigmentation issues (i.e. darkening of the lips)?	Does anyone else in your biological family have dark lips?	Do you suffer with any other hyperpigmentation elsewhere about your body?	Do you smoke?	Do you drink hot drinks?	How many litres of water do you drink per day?	Do you wear lipstick daily?	Do you suck your lips?	Do you have dry, sensitive or chapped lips?	Does hyperpigmented lips affect your confidence, happiness or quality of life?
1	No	Yes	No			No	No	Yes	No	Yes	1	No	Yes	Yes	Yes
2	No	Yes	Yes	No		No	Yes	Yes	No	Yes	1	No	Yes	Yes	Yes
3	Yes	Yes	No			No	No	Yes	No	Yes	2	No	Yes	Yes	Yes
4	Yes	Yes	No			No	No	Yes	No	Yes	0	No	No	Yes	Yes
5	No	No	No			No	Yes	No	No	Yes	2	No	Yes	Yes	No
6	Yes	Yes	Yes	No		No	No	Yes	No	Yes	2	Yes	No	Yes	Yes
7	No	No	No			No	Yes	Yes	No	Yes	2	No	Yes	Yes	Yes
8	Yes	Yes	Yes	No		No	Yes	Yes	No	Yes	1	Yes	No	Yes	Yes
9	No	Yes	No			No	Yes	Yes	No	Yes	1	No	No	Yes	Yes
10	No	Yes	No			No	Yes	Yes	No	Yes	2	Yes	No	No	No
11	No	Yes	No			No	Yes	No	No	Yes	2	Yes	No	Yes	No
12	No	No	No			No	Yes	Yes	No	Yes	1	No	No	Yes	No
13	Yes	Yes	No			No	Yes	No	No	Yes	2	No	No	No	No
14	Yes	Yes	No			No	No	Yes	No	Yes	1	Yes	No	Yes	Yes
15	Yes	Yes	No			No	Yes	Yes	No	Yes	2	No	No	Yes	Yes
16	Yes	Yes	Yes	No		No	Yes	Yes	No	Yes	1	No	No	Yes	Yes
17	Yes	Yes	No			No	Yes	Yes	Yes	Yes	0	No	Yes	Yes	Yes
18	No	Yes	No			No	Yes	Yes	No	No	2	No	No	Yes	Yes
19	No	No	No			No	No	No	No	Yes	2	No	No	No	No
20	Yes	Yes	No			No	Yes	Yes	No	Yes	2	Yes	No	Yes	No
21	Yes	Yes	Yes	No		No	No	Yes	No	Yes	1	No	No	No	Yes
22	No	Yes	No			No	Yes	Yes	No	Yes	2	Yes	Yes	Yes	Yes
23	Yes	Yes	No			No	Yes	Yes	No	Yes	3	No	No	Yes	No
24	No	Yes	Yes	No		No	Yes	Yes	No	Yes	1	Yes	No	Yes	No
Yes (Count)	12	20	6	0	0	0	17	20	1	23	0	8	7	20	15
No (Count)	12	4	18	6	0	24	7	4	23	1	0	16	17	4	9
Yes (%)	50.00%	83.33%	25.00%	0.00%	-	0.00%	70.83%	83.33%	4.17%	95.83%	-	33.33%	29.17%	83.33%	62.50%
No (%)	50.00%	16.67%	75.00%	100.00%	-	100.00%	29.17%	16.67%	95.83%	4.17%	-	66.67%	70.83%	16.67%	37.50%

After 3 months of use summary

Time Interval	Description	Question Ref.	Statement to be evaluated	Positive Response %	Responses	% Pass Criteria	Verdict
1	After 3 months of use	1	After 3 months of use, my lip pigmentation has lightened.	100%	24	68.00%	Passed
1	After 3 months of use	2	After 3 months of use, dark spots on my lips have visibly reduced.	100%	24	68.00%	Passed
1	After 3 months of use	3	After 3 months of use, my lip tone has been evened.	100%	24	68.00%	Passed
1	After 3 months of use	4	After 3 months of use, my lips feel less sensitive.	100%	24	68.00%	Passed
1	After 3 months of use	5	After 3 months of use, my lips feel more hydrated.	92%	24	68.00%	Passed
1	After 3 months of use	6	After 3 months of use, I feel the product has improved the appearance of my lips.	100%	24	68.00%	Passed
1	After 3 months of use	7	After 3 months of use, I am more confident about my appearance.	88%	24	68.00%	Passed
1	After 3 months of use	8	After 3 months of use, I feel happier about the appearance of my lips.	96%	24	68.00%	Passed

After 6 months of use summary

Time Interval	Description	Question Ref.	Statement to be evaluated	Positive Response %	Responses	% Pass Criteria	Verdict
2	After 6 months of use	9	After 6 months of use, my lip pigmentation has lightened.	96%	24	68.00%	Passed
2	After 6 months of use	10	After 6 months of use, dark spots on my lips have visibly reduced.	92%	24	68.00%	Passed
2	After 6 months of use	11	After 6 months of use, my lip tone has been evened.	92%	24	68.00%	Passed
2	After 6 months of use	12	After 6 months of use, my lips feel less sensitive.	92%	24	68.00%	Passed
2	After 6 months of use	13	After 6 months of use, my lips feel more hydrated.	96%	24	68.00%	Passed
2	After 6 months of use	14	After 6 months of use, I feel the product has improved the appearance of my lips.	92%	24	68.00%	Passed
2	After 6 months of use	15	After 6 months of use, I am more confident about my appearance.	96%	24	68.00%	Passed
2	After 6 months of use	16	After 6 months of use, I feel happier about the appearance of my lips.	92%	24	68.00%	Passed
2	After 6 months of use	17	I enjoyed using the Lip Care Kit.	88%	24	68.00%	Passed
2	After 6 months of use	18	I found the Lip Care Kit easy to use.	88%	24	68.00%	Passed
2	After 6 months of use	19	I would recommend the Lip Care Kit to friends with lip pigmentation issues.	92%	24	68.00%	Passed

Criteria for Validation of Claims

The following validation criteria are used for analysis of the intended claims where possible;

When N is ≥ 90 to ≤ 115 , the **PO** must exceed 68%

When N is < 90 or > 115 the **PO** must exceed $RP + 1.645 * \sqrt{(RP * (1 - RP)/N)}$

Where;

RP = Reference Percentage

N = Sample Size

PO = Percentage Observed

Additional validation criteria are...

Condition 1 = Total of responses is > 30

Condition 2 = $N \text{ Pref}(1\text{-Pref}) > 5$

Adverse Reactions & Undesirable Effects

Overview

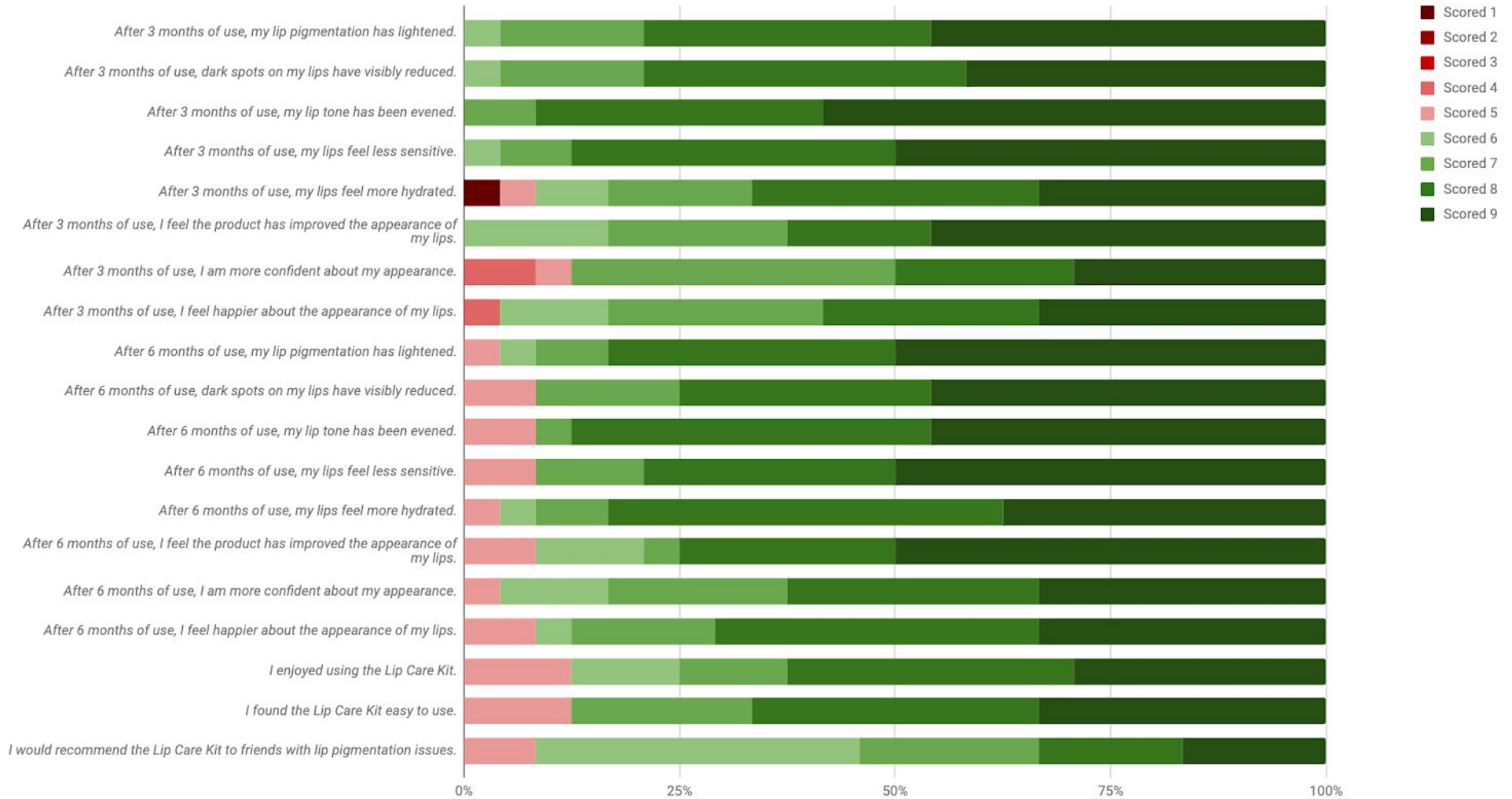
Adverse Reactions Recorded	0
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Further Analysis of Results

Percentage Share of Scale

Description	Question Ref.	Statement to be evaluated	Scored 1	Scored 2	Scored 3	Scored 4	Scored 5	Scored 6	Scored 7	Scored 8	Scored 9	Count of Responses	Positive Responses
After 3 months of use	1	After 3 months of use, my lip pigmentation has lightened.	0.00%	0.00%	0.00%	0.00%	0.00%	4.17%	16.67%	33.33%	45.83%	24	100.00%
After 3 months of use	2	After 3 months of use, dark spots on my lips have visibly reduced.	0.00%	0.00%	0.00%	0.00%	0.00%	4.17%	16.67%	37.50%	41.67%	24	100.00%
After 3 months of use	3	After 3 months of use, my lip tone has been evened.	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	8.33%	33.33%	58.33%	24	100.00%
After 3 months of use	4	After 3 months of use, my lips feel less sensitive.	0.00%	0.00%	0.00%	0.00%	0.00%	4.17%	8.33%	37.50%	50.00%	24	100.00%
After 3 months of use	5	After 3 months of use, my lips feel more hydrated.	4.17%	0.00%	0.00%	0.00%	4.17%	8.33%	16.67%	33.33%	33.33%	24	91.67%
After 3 months of use	6	After 3 months of use, I feel the product has improved the appearance of my lips.	0.00%	0.00%	0.00%	0.00%	0.00%	16.67%	20.83%	16.67%	45.83%	24	100.00%
After 3 months of use	7	After 3 months of use, I am more confident about my appearance.	0.00%	0.00%	0.00%	8.33%	4.17%	0.00%	37.50%	20.83%	29.17%	24	87.50%
After 3 months of use	8	After 3 months of use, I feel happier about the appearance of my lips.	0.00%	0.00%	0.00%	4.17%	0.00%	12.50%	25.00%	25.00%	33.33%	24	95.83%
After 6 months of use	9	After 6 months of use, my lip pigmentation has lightened.	0.00%	0.00%	0.00%	0.00%	4.17%	4.17%	8.33%	33.33%	50.00%	24	95.83%
After 6 months of use	10	After 6 months of use, dark spots on my lips have visibly reduced.	0.00%	0.00%	0.00%	0.00%	8.33%	0.00%	16.67%	29.17%	45.83%	24	91.67%
After 6 months of use	11	After 6 months of use, my lip tone has been evened.	0.00%	0.00%	0.00%	0.00%	8.33%	0.00%	4.17%	41.67%	45.83%	24	91.67%
After 6 months of use	12	After 6 months of use, my lips feel less sensitive.	0.00%	0.00%	0.00%	0.00%	8.33%	0.00%	12.50%	29.17%	50.00%	24	91.67%
After 6 months of use	13	After 6 months of use, my lips feel more hydrated.	0.00%	0.00%	0.00%	0.00%	4.17%	4.17%	8.33%	45.83%	37.50%	24	95.83%
After 6 months of use	14	After 6 months of use, I feel the product has improved the appearance of my lips.	0.00%	0.00%	0.00%	0.00%	8.33%	12.50%	4.17%	25.00%	50.00%	24	91.67%
After 6 months of use	15	After 6 months of use, I am more confident about my appearance.	0.00%	0.00%	0.00%	0.00%	4.17%	12.50%	20.83%	29.17%	33.33%	24	95.83%
After 6 months of use	16	After 6 months of use, I feel happier about the appearance of my lips.	0.00%	0.00%	0.00%	0.00%	8.33%	4.17%	16.67%	37.50%	33.33%	24	91.67%
After 6 months of use	17	I enjoyed using the Lip Care Kit.	0.00%	0.00%	0.00%	0.00%	12.50%	12.50%	12.50%	33.33%	29.17%	24	87.50%
After 6 months of use	18	I found the Lip Care Kit easy to use.	0.00%	0.00%	0.00%	0.00%	12.50%	0.00%	20.83%	33.33%	33.33%	24	87.50%
After 6 months of use	19	I would recommend the Lip Care Kit to friends with lip pigmentation issues.	0.00%	0.00%	0.00%	0.00%	8.33%	37.50%	20.83%	16.67%	16.67%	24	91.67%

Graphical Share of Scale



Appendices

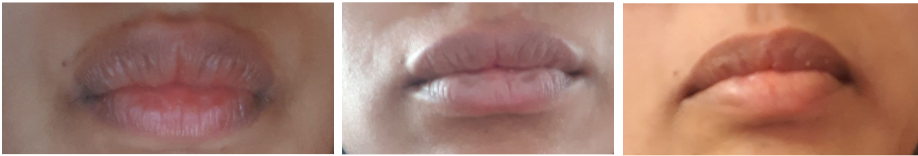
Appendix 1 - Product Literature & Further Information

Left Photo; Pre-Assessment, Centre Photo; 3 month, Right Photo; 6 month

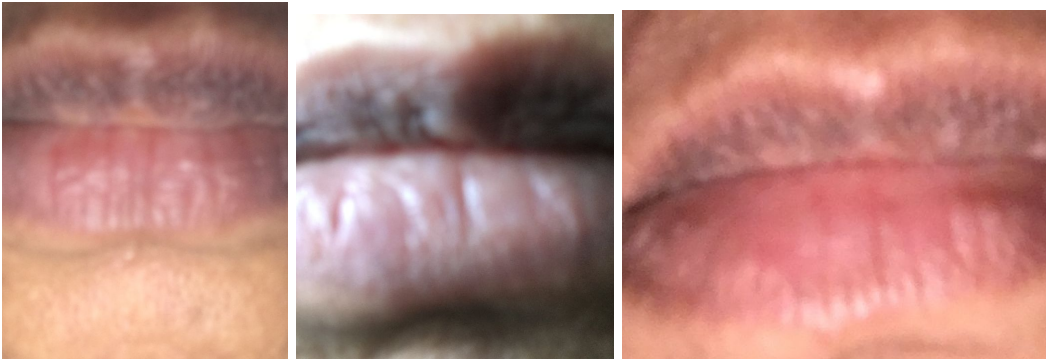
Subject 1



Subject 2



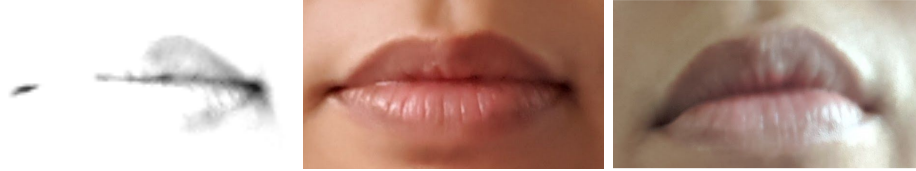
Subject 3



Subject 4



Subject 5



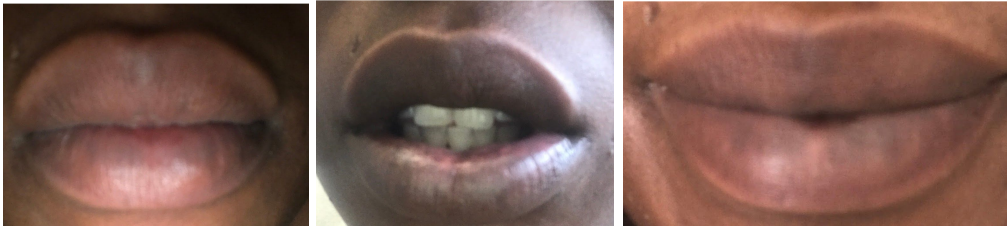
Subject 6



Subject 7



Subject 8



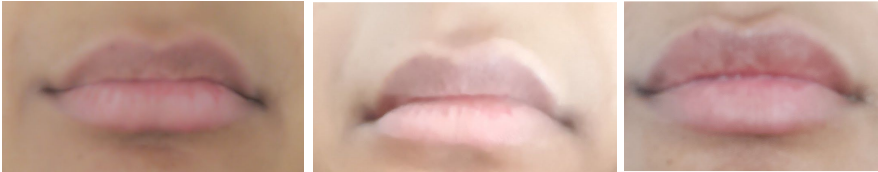
Subject 9



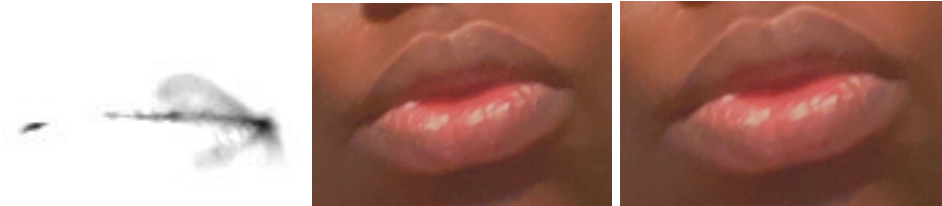
Subject 10



Subject 11



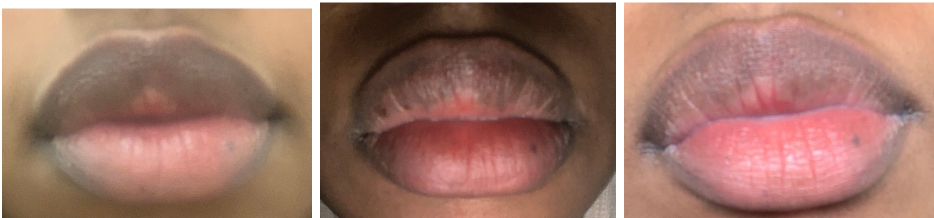
Subject 12



Subject 13



Subject 14



Subject 15



Subject 16



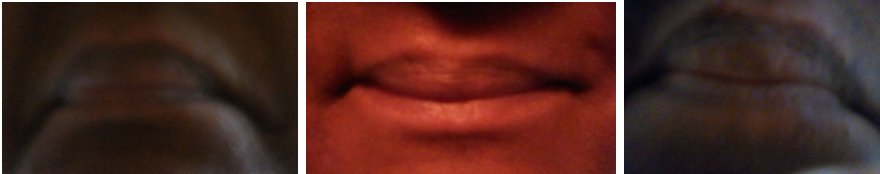
Subject 17



Subject 18



Subject 19



Subject 20



Subject 21



Subject 22



Subject 23



Subject 24



Appendix 2 - Regulatory Objective

This study has been conducted in respect of part of European Commission Regulation 655/2013 and the bigger umbrella of EC 1223 which lays out the criteria for the justification of claims used in relation to cosmetic products. The trial was conducted in respect of the *Helsinki Declaration* (Helsinki Declaration 64th WMA General Assembly, Fortaleza, Brazil, October 2013) relating to ethical principles for research involving human subjects.

European Commission Regulation 655/2013 dictates specifically that criteria for assessment of a cosmetic product comprises of;

- Legal compliance
- Truthfulness
- Evidential support
- Honesty
- Fairness
- Informed decision making

The primary objective of this study relates to the provision of evidential support. Evidential support includes the following sub-categories;

- Consumer feedback data
- Clinical evaluation data
- Product nature data
- Formulation data
- Supporting ingredient data

Appendix 3 - Oversight Credentials & Quality Assurance

This study was conducted from the stated study centre with relevant company and individual qualification including;

Company

- Accreditation according to ISO 9001:2008
- Accreditation according to ISO 17025:2005

Competent Employees

- BSc (Hons) App. Chem CSci, CChem FRSC, PhD
- Fellow of the Royal Society Of Chemistry and a "Chartered" Chemist and Scientist
- Members of The Society Of Cosmetic Scientists
- Members of the British Toxicology Society
- Members of Society of Dermatology
- Members of International Society of Dermoscopy
- Members of European Academy of Dermatology & Venereology (EADV)
- Members on the Editorial board of the journal Dermatopathology

Study Results and Observations

This report is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study. The reported results relate exclusively to the tested sample and was administered from the stated study centre.



Andrew James
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