

Skin Pigmentation Regression test

Study TR19020

Conducted for

Corium Health

by Eurofins Dermatest Pty Ltd

11 Subjects

Products:

Microskin Simulated Second Skin: Golden Russet

Single Application – One Week

February 2019

1.Objective

This panel was convened to evaluate the in-use performance of treatment preparation intended for application to skin for artificial tanning. The biophysical effect of skin colour change after a single application of the topically applied product was evaluated versus the pre-treatment background colour. 11 subjects were recruited for the study, with all completed results for all tabulated.

2. Test Material Handling

Three test samples labeled Microskin Simulated Second Skin: Golden Russet (Product A), was received from Corium Health. Upon arrival at Dermatest, the test material was assigned a unique laboratory code number TR19020 and entered into a log identifying the lot number, sample description, sponsor, date received and tests requested. The study was commenced on 4/02/19 and ended on 11/02/19.

3. Standards for Inclusion in a Study:

1. Individuals between the ages of 21 to 70.
2. Individuals who's sex was Male or Female.
3. Individuals who's race was Asian and Caucasian.
4. Individuals who did not have tanned skin.
5. Individuals not taking medication or under the care of a physician for a period of one month prior to commencement and throughout the entire test period.
6. Individuals who have completed a preliminary medical history mandated by Eurofins Dermatest.
7. Individuals who have read, understood and signed an informed consent document. Consent forms are kept on file and are available for examination on the premises of Eurofins Dermatest.
8. Individuals who understands and instructions for use and are willing to cooperate with the program as stated.
9. Individuals free of any dermatological or systemic disorder that would interfere with the results, at the discretion of the Investigator.
10. Individuals able to cooperate with the Investigator and the research staff, be willing to complete the full course of the study.

4. Standards for Exclusion from a Study:

1. Individuals who are under doctors care.
2. Individuals who are currently taking medication which in the opinion of the investigator would mask or interfere with the results.
3. Individuals with any history of sensitivity to cosmetics in general and moisturisers in particular.
4. Individuals with any form of skin cancer, melanoma, lupus, psoriasis, rosacea, porphyria cutanea tarda, connective tissue disease, or any disease that would interfere with the test results. Individuals diagnosed with chronic skin allergies.
5. Female volunteers who indicate that they are pregnant or nursing an infant.
6. Individuals with excessive hair on the test sites.
7. Individuals with known hypersensitivity to cosmetic products.

5. Informed Consent:

TR19020

1. A signed informed consent was obtained from each panelist prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability.
2. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms are available for inspection on the premises of Eurofins Dermatest.

6. Preparation

1. In order to pre condition the test sites and keep all topical treatments constant for all test subjects, panelists were required to abstain from using skin tanning products and treatments on the test area for a period of one month prior to study commencement. At the completion of the one month 'washout' period, panelists were required to return to the test facility at the time specified by the technician for the study commencement.
2. On the first day of the study, biophysical measurements were taken at $t = 0$ (pre application). Test material was applied to a inner forearm by the clinician to the panelists. The amount applied using a stipple, as instructed by the client.
3. Panelists were told to avoid strenuous exercise and use of other
4. Panelist were instructed to return to the laboratory at 1 day, 2 days, 4 days and 7 days after single application.
5. The data from all 11 test subjects was compiled in order to arrive at average changes for each time point i.e. the shift from initial skin colour.

7. Application of Skin Tanning Preparations.

An area of consistently and representatively pigmented skin was selected. The target area was the under arm for each product.

The area was mapped for corresponding measurement at the further timepoints.

Tristimulus colour measurements were taken using a Minolta Cm-2600

Spectrophotometer. This instrument computes the colour values in the $L^*a^*b^*$ colour space. L^* indicates lightness (+ = lighter, - = darker), a^* is the red/green coordinate (+ = redder, - = greener), and b^* is the yellow/blue (+ = yellower, - = bluer) coordinate.

The total colour change was calculated by the Euclidean distance (ΔE) calculated by:

$$\Delta E_{ab}^* = \sqrt{(L_2^* - L_1^*)^2 + (a_2^* - a_1^*)^2 + (b_2^* - b_1^*)^2}$$

8. Method

Mean total colour change was calculated at the $T=1, 2, 4$ and 7 time points compared with immediately prior to the start of the study. Measurements were in the $L^*a^*b^*$ scale and were tabulated for both SCI (specular component included) and SCE (specular component excluded) values. For Total Colour Shift and SCI values are reported.

For the purposes of this hypothesis the a^* value was not incorporated as a test parameter due to the physiological variables e.g. test subjects being too hot on any given reading, the instrument being pushed too hard into the skin, etc.

9. Results

9.1. Total Colour Change

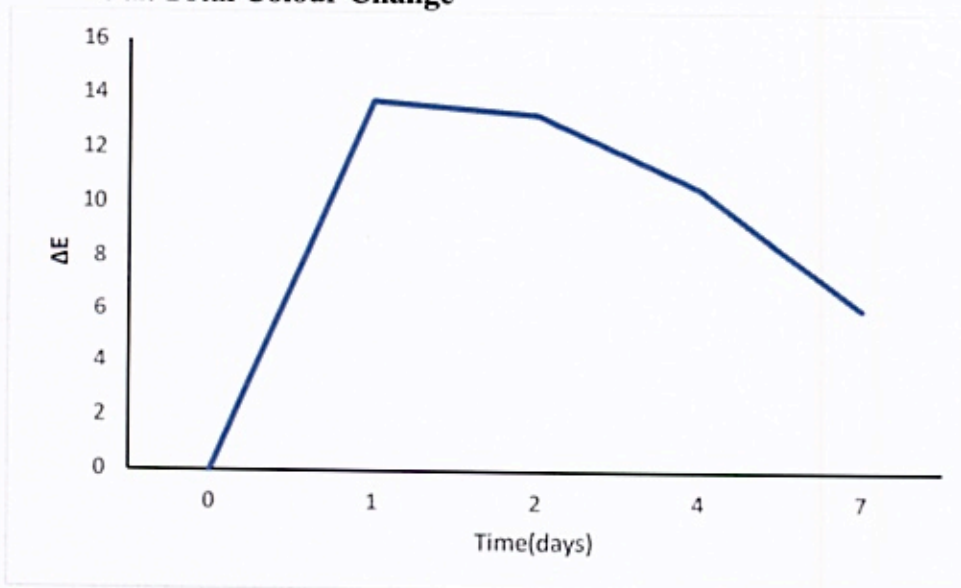


Figure 1: Mean total colour change (ΔE) vs time of Microskin Simulated Second Skin: Golden Russet (n=11)

9.2. Darkening .

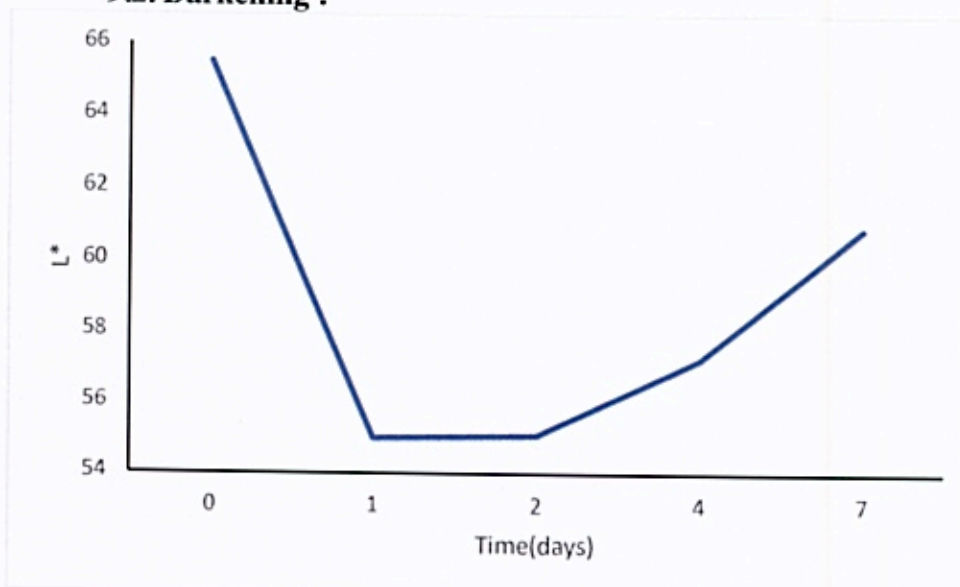


Figure 2: Mean L^* vs time of Microskin Simulated Second Skin: Golden Russet (n=11)

10. Interpretation

Minolta Colour Computer Measurement

The product exhibited activity in increasing skin pigmentation as reflected in the total colour change and the L^* value (black to white) shift of the pigmented areas over the time of the study. This change was instrumentally discriminated. The effect on background was monitored however further statistical analysis would be needed to determine whether or not the shift was significant.

10.1 Total Colour change

Microskin Simulated Second Skin: Golden Russet showed increased change of 13.78 rapid colour build and slightly more intensity.

10.2 Skin Darkening

Microskin Simulated Second Skin: Golden Russet showed more rapid colour build indicative of skin darkening.

11. Adverse Events

No adverse effects were observed.

12. References

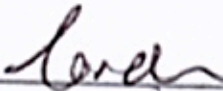
1. Dermatest SOP DESOP 121 Tanning Regression using the Konica Minolta CM-2600 Spectrophotometer.
2. Spectrophotometer Cm-2660d/2500d Instruction Manual – Konica Minolta.
3. Katherine, L, Domingo, M, Franco, P, & Jorge, L 2006, 'Color measurement in L*a*b* units from RGB digital images', *Food Research International*, vol. 40, pp. 1084-1091.

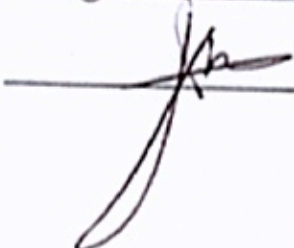
13. Archiving:

All original samples, raw data sheets, technicians notebooks, correspondence files, copies of final reports and remaining specimens are maintained on the premises of Dermatest, in limited access storage files. A duplicate disk copy of final report is separately archived offsite.

14. Conclusion:

In conclusion, the product, Microskin Simulated Second Skin: Golden Russet, showed an immediate mean colour change at t=1 (fig1). This change in mean colour in conjunction with the 16% drop in the L* value correlates to a successful darkening of the skin, when compared to baseline readings (fig2). The L* parameters remained consistently lower than the baseline values throughout and at the end of the testing period representing a 7% drop.

Technician Signature: 

Study Director Signature: 

Subject ID	t=0			t=1				t=2			
	L*	a*	b*	L*	a*	b*	ΔE	L*	a*	b*	ΔE
TR01	64.47	4.96	17.80	55.07	11.84	22.22	12.5	56.40	11.42	22.35	11.3
TR02	65.96	5.50	16.34	53.86	11.87	21.35	14.6	53.99	11.03	20.32	13.8
TR03	63.24	5.47	15.29	55.20	10.61	20.48	10.9	55.54	10.57	19.84	10.3
TR04	64.51	3.96	12.77	54.31	12.06	20.14	15.0	53.36	11.71	20.14	15.4
TR05	64.80	5.29	17.22	53.24	11.42	21.77	13.9	57.04	9.73	21.29	9.8
TR06	68.70	5.20	15.06	54.61	12.74	21.87	17.4	56.71	11.57	21.22	14.9
TR07	72.21	2.86	13.17	56.39	11.95	21.86	20.2	53.67	11.39	20.95	21.8
TR08	61.55	6.65	17.35	53.17	8.60	17.27	8.6	51.62	8.15	17.30	10.0
TR09	58.58	5.76	13.60	53.60	10.72	19.44	9.1	53.72	10.76	18.07	8.3
TR10	73.00	2.23	7.23	61.10	9.52	18.20	17.8	59.72	8.95	18.86	18.9
TR11	63.45	4.86	16.93	54.37	11.01	21.35	11.8	53.91	10.72	20.42	11.7
Mean	65.50	4.79	14.80	54.99	11.12	20.54	13.78	55.06	10.55	20.07	13.30

Subject ID	t=3				t=4			
	L*	a*	b*	ΔE	L*	a*	b*	ΔE
TR01	57.35	9.98	19.99	10.5	58.78	8.88	19.55	7.1
TR02	62.23	6.54	16.34	3.9	65.15	6.45	16.00	1.3
TR03	57.46	8.64	18.58	7.4	60.89	8.08	16.38	3.7
TR04	53.78	9.50	16.19	12.6	56.08	9.47	15.77	10.5
TR05	61.00	7.70	20.94	5.8	60.88	7.36	20.21	5.3
TR06	60.79	8.87	18.53	9.4	68.33	5.88	13.85	1.4
TR07	54.89	11.13	20.90	20.7	59.78	8.73	17.83	14.5
TR08	54.72	7.08	17.42	6.8	56.87	7.12	15.88	4.9
TR09	54.88	8.83	16.48	5.6	55.26	9.43	15.74	5.4
TR10	57.65	11.50	22.47	23.5	70.60	3.53	9.96	3.9
TR11	54.53	8.82	19.44	10.1	56.81	9.39	19.83	8.5
Mean	57.19	8.86	18.73	10.58	60.86	7.67	16.45	6.06