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Tradename: Phytofuse Rejuvenate®

Code: 16882

CAS #: 93384-40-8

Test Request Form #: 995

Lot #: NC140105-A

Sponsor: Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092

Study Director: Erica Segura

Principle Investigator: Maureen Danaher

Test Performed:

High Resolution Ultrasound Skin-Imaging Assay

Introduction

An *in-vivo* study was conducted over a period of four weeks to evaluate the effect on skin density of **Phytofuse Rejuvenate®**. Ten M/F subjects between the ages of 23-45 participated in the study. Data gathered from the high resolution ultrasound imaging yielded results that indicate that this material is capable of significantly improving skin density compared to the control.

Materials

A. Equipment: DermaLab Skin Combo (Ultrasound Probe)

Methods

High Resolution Ultrasound Skin imaging is based on measuring the acoustic response after an acoustic pulse is sent into the skin. The energy of the acoustic pulse is low and will not affect the skin in any way. When the acoustic pulse is emitted and hits different areas of the skin, part of the pulse will be reflected and part will be transmitted further into the skin. The reflected signal travels back and is picked up by the ultrasound transducer. After processing the signal, a cross-sectional image appears on the screen. This image represents an intensity, or amplitude, analysis of the signals.

The intensity of the signals that are received refer to a color scale. Dark colors represent areas of the skin with low reflection. This means that there are no changes or very small changes in density between the structures in the skin. Bright colors represent areas with strong reflections, signifying substantial changes in density between structures.

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Ten volunteers M/F between the ages of 23 and 45 and who were known to be free of any skin pathologies participated in this study. The DermaLab ultrasound probe was used to determine the skin density of the subject's volar forearms.

Following initial measurements, all subjects were asked to apply 2 mg of each test material on their volar forearms. Measurements were taken 24 hours after application of test materials and then weekly for 4 weeks. The test material consisted of 2.0% **Phytofuse Rejuvenate**® in a base lotion.

For added perspective, measurements of an untreated test site and a site treated with a base lotion (Cetaphil Moisturizing for All Skin Types) were recorded.

Results

Phytofuse Rejuvenate® showed improvements in skin density at a 2.0% concentration. Please note, each value is an average of three consecutive readings per test site.

Ultrasound		T = 24 Hours	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks
Panelist 1	Experimental	45	53	53	60	68
	Base Lotion	60	61	55	59	60
	Untreated	74	71	68	70	72
Panelist 2	Experimental	75	78	75	78	82
	Base Lotion	76	80	78	77	75
	Untreated	60	60	53	55	61
Panelist 3	Experimental	63	58	56	65	70
	Base Lotion	60	68	70	73	77
	Untreated	65	63	57	60	62
Panelist 4	Experimental	73	97	100	112	130
	Base Lotion	64	66	64	68	70
	Untreated	50	66	65	59	60
	Experimental	60	70	71	75	76
Panelist 5	Base Lotion	61	62	63	65	67
	Untreated	71	72	75	76	79
Panelist 6	Experimental	72	62	62	72	75
	Base Lotion	50	58	57	59	65
	Untreated	27	28	36	35	34
	Experimental	81	84	92	100	100
Panelist 7	Base Lotion	45	50	53	51	53
	Untreated	88	90	85	90	83
	Experimental	52	52	54	55	56
Panelist 8	Base Lotion	79	77	74	77	73
	Untreated	58	55	53	46	56
	Experimental	81	84	87	89	90
Panelist 9	Base Lotion	67	64	66	68	65
	Untreated	75	74	75	73	82
Panelist 10	Experimental	57	59	62	63	66
	Base Lotion	58	52	45	45	51
	Untreated	57 10	55	41	43	46
Number	Number of Panelists		10	10	10	10

Figure 1: Individual Raw Data

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	T = 24	1 week	2 week	3 week	4 week
Experimental (2.0% Phytofuse Rejuvenate® in Base Lotion)	65.9	69.7	71.2	76.9	81.3
Untreated Control	62.5	63.4	60.8	60.7	63.5
Base Lotion Control	62.0	63.8	62.5	64.2	65.6

Figure 2: Average values

	T = 24	1 week	2 week	3 week	4 week
Base Lotion vs. Untreated	-0.80%	0.63%	2.80%	5.77%	3.31%
Experimental vs. Untreated	5.44%	9.94%	17.11%	26.69%	28.03%
Experimental vs. Base Lotion	6.29%	9.25%	13.92%	19.78%	23.93%

Figure 3: Percent change

Comparative Analysis of Skin Density

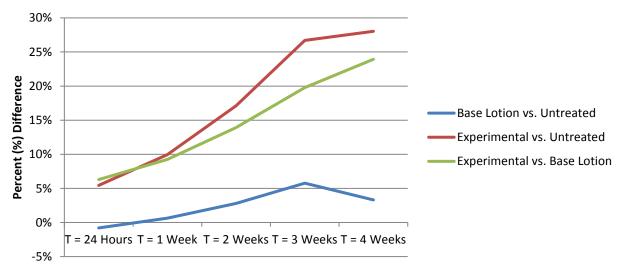


Figure 4: Percent difference in skin density recordings between test materials

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Discussion

As evidenced in a 4 week efficacy study of **Phytofuse Rejuvenate**® on skin, skin density was improved by 5.44% after 24 hours and by 28.03% after 4 weeks when compared to the untreated control. When compared to the base cream **Phytofuse Rejuvenate**® improved skin density by 6.29% after 24 hours and after 4 weeks **Phytofuse Rejuvenate**® improved density by 23.93%. Results indicate that **Phytofuse Rejuvenate**® is capable of improving skin density when compared to both the untreated control as well as the base lotion.

Phytofuse Rejuvenate® has a positive effect on skin's density when used at recommended use levels.

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