



High Resolution Ultrasound Skin Imaging Assay

info@activeconceptsllc.com • Phone: +1-704-276-7100 • Fax: +1-704-276-7101

Tradename: Phytofuse Renew®

Code: 16586

CAS #: 90106-73-3

Test Request Form #: 3969

Lot #: NC180213-C

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 Renew®**. 10 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.



High Resolution Ultrasound Skin Imaging Assay

info@activeconceptsllc.com • Phone: +1-704-276-7100 • Fax: +1-704-276-7101

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

Individual Raw Data:

	t = 24	1 week	2 weeks	3 weeks	4 weeks
Subject 1-Test	64	65	91	62	63
Untreated Control	48	51	48	47	51
Base Lotion Control	52	61	66	60	71
Subject 2-Test	48	44	55	61	65
Untreated Control	68	78	81	75	82
Base Lotion Control	78	98	99	93	100
Subject 3-Test	75	75	69	73	74
Untreated Control	70	76	63	78	78
Base Lotion Control	37	46	35	41	52
Subject 4-Test	77	66	78	76	87
Untreated Control	39	30	41	49	53
Base Lotion Control	57	62	62	71	72
Subject 6-Test	73	78	0	78	78
Untreated Control	71	56	0	76	78
Base Lotion Control	31	37	0	36	45

Information contained in this technical literature is believed to be accurate and is offered in good faith for the benefit of the customer. The company, however, cannot assume any liability or risk involved in the use of its chemical products since the conditions of use are beyond our control. Statements concerning the possible use of our products are not intended as recommendations to use our products in the infringement of any patent. We make no warranty of any kind, expressed or implied, other than that the material conforms to the applicable standard specification.



High Resolution Ultrasound Skin Imaging Assay

info@activeconceptsllc.com • Phone: +1-704-276-7100 • Fax: +1-704-276-7101

	T = 24	1 week	2 weeks	3 weeks	4 weeks
Subject 7-Test	48	0	68	63	64
Untreated Control	48	0	65	64	58
Base Lotion Control	30	0	62	37	55
Subject 8-Test	55	42	49	51	51
Untreated Control	84	81	92	83	96
Base Lotion Control	68	64	83	79	82
Subject 9-Test	39	47	41	45	42
Untreated Control	47	45	53	55	54
Base Lotion Control	47	51	60	54	64
Subject 10-Test	77	84	86	65	81
Untreated Control	52	70	70	77	72
Base Lotion Control	69	80	78	78	82

Raw Data:

	t=24	1 week	2 week	3 week	4 week
Experimental (2.0% Phytofuse Renew® in Base Lotion)	69.2	72.5	75.0	77.4	75.5
Untreated Control	52.1	50.1	51.1	54.0	53.9
Base Lotion Control	59.0	58.8	61.2	61.4	60.1
	t=24	1 week	2 week	3 week	4 week
Experimental vs. Untreated	32.82%	44.88%	46.76%	43.28%	40.10%
Base Lotion vs. Untreated Control	13.24%	17.44%	19.82%	13.57%	11.54%
Experimental vs. Base Lotion	17.29%	23.36%	22.49%	26.16%	25.60%

Information contained in this technical literature is believed to be accurate and is offered in good faith for the benefit of the customer. The company, however, cannot assume any liability or risk involved in the use of its chemical products since the conditions of use are beyond our control. Statements concerning the possible use of our products are not intended as recommendations to use our products in the infringement of any patent. We make no warranty of any kind, expressed or implied, other than that the material conforms to the applicable standard specification.



High Resolution Ultrasound Skin Imaging Assay

info@activeconceptsllc.com • Phone: +1-704-276-7100 • Fax: +1-704-276-7101

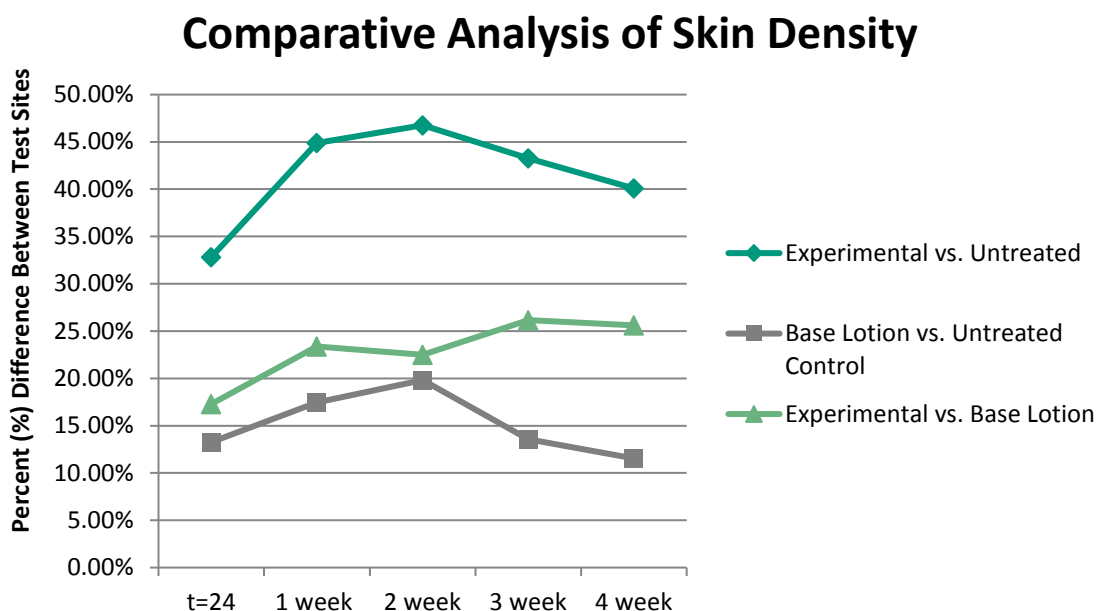


Figure 1: Percent difference in skin density recordings between test materials

Discussion

As evidenced in a 4 week efficacy study of **Phytofuse Renew**® on skin, skin density was improved by 32.82% after 24 hours and by 40.10% after 4 weeks when compared to the untreated control. When compared to the base cream **Phytofuse Renew**® improved skin density by 17.29% after 24 hours and after 4 weeks **Phytofuse Renew**® improved density by 25.60%. Results indicate that **Phytofuse Renew**® is capable of improving skin density when compared to both the untreated control as well as the base lotion.

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