

High Resolution Skin Imaging Assay

ACTIVE CONCEPTS LLC

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Tradename: AC Vegetable Ceramides G

<u>Code:</u> 16558G

CAS #: 56-81-5 & 308067-30-3

Test Request Form #: 10778

Lot #: 9395464

Sponsor: Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092 Study Director: Maureen Drumwright Principle Investigator: Kayla Patterson

Test Performed:

High Resolution Ultrasound Skin-Imaging Assay

Introduction

Collagen is the most abundant protein that can be found in the skin and other areas of the body. Collagen encourages the top layer of skin to regenerate which in return keeps skin looking healthy and youthful. Collagen naturally decreases with age and can result in sagging, wrinkles, and fine lines.

The High-Resolution Ultrasound Skin Imaging Assay was conducted to assess the ability of **AC Vegetable Ceramides G** to enhance skin density.

Assay Principle

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 in 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 refers 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. The epidermis is characterized by a high intensity white/yellow color while the dermis is a mixture of colors at varying intensities.

Materials

A. Equipment: DermaLab Skin Combo (Ultrasound Probe)

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Methods

Twenty male and female volunteers between the ages of 23 and 45 who were known to be free of any skin participated in this study. A Dermalab Ultrasound probe was used to measure skin density values on the subject's volar forearms. The Dermalab software automatically detects the epidermis edge and calculates a collagen score for each image. The higher the levels of skin density, the higher the readings from the Ultrasound Probe will be. Baseline density readings were taken on the first day of the study.

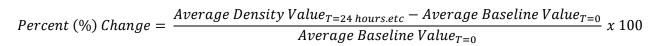
Following initial measurements, subjects were instructed to apply 0.2 g of each treatment to their volar forearm twice a day for a four-week period. Measurements were taken weekly for four weeks.

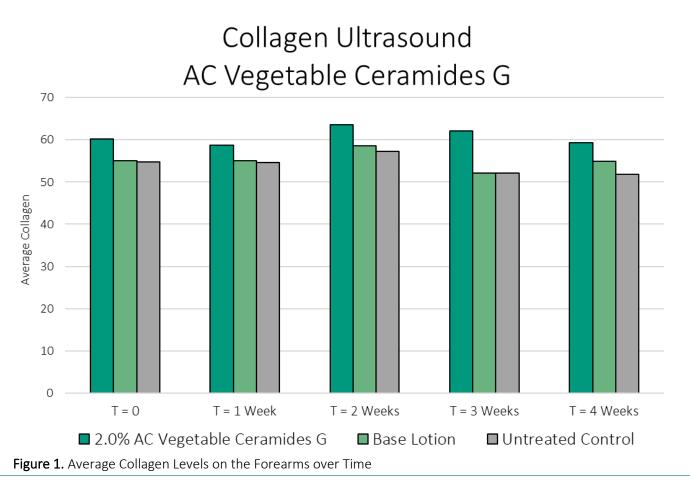
For added perspective, measurements of an untreated test site and a site treated with a base lotion (Cetaphil Moisturizing for All Skin Types) were recorded.

<u>Results</u>

AC Vegetable Ceramides G showed improvements in skin density at a 2.0% concentration. Please note each value is an average of three consecutive readings per test site.

Percent change in density is calculated by the following formula:





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Table 1. Difference in Skin Density Levels between Test Materials at Each Time Point

Percent (%) Difference	Baseline	1 Week	2 Weeks	3 Weeks	4 Weeks
Experimental (2.0% AC Vegetable					
Ceramides G + Base Lotion) vs Base	9%	7%	8%	19%	8%
Lotion					
Experimental (2.0% AC Vegetable					
Ceramides G + Base Lotion) vs	10%	7%	11%	19%	10%
Untreated Control					
Base Lotion vs Untreated Control	9%	7%	8%	19%	8%

Discussion

Skin density was improved as evidenced in this four-week efficacy study of **AC Vegetable Ceramides G** on skin. On average the product containing 2.0% **AC Vegetable Ceramides G** performed better than both the base lotion and the untreated control (Figure 1). When compared to the base lotion, 2.0% **AC Vegetable Ceramides G** had 8% higher skin density after 4 weeks (Table 1). Additionally, skin density was 10% higher at the site treated with 2.0% **AC Vegetable Ceramides G** in a lotion base is capable of increasing skin density to a greater degree when compared to the base lotion and untreated control.

With the present study, we can confirm that **AC Vegetable Ceramides G** is capable of improving skin density when added to personal care applications at recommended use levels.

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