

**Tradename:** AC Dermal Respiratory Factor PF

**Code:** 20219PF

**CAS #:** 7732-18-5 & 8013-01-2

**Test Request Form #:** 811

**Lot #:** NC140218-A

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

**Study Director:** *Erica Segura*

**Principle Investigator:** *Meghan Darley*

**Test Performed:**

Pigmentation Assay

**Introduction**

Skin pigmentation refers to the color of skin and is a result of the production of melanin. Melanin protects cells from sun damage by absorbing harmful UV rays and distributing it to the upper layers of skin. Low amounts of melanin in the skin leads to a higher chance of UV skin damage. When skin is damaged by harmful UV rays, the appearance of premature ageing often occurs.

The pigmentation assay was conducted to assess the effects of **AC Dermal Respiratory Factor Advanced PF**.

**Assay Principle**

The pigmentation module provides information about the skin's pigmentation and erythema levels with measurement based on an active color detecting chip. This measurement of the DermaLab Combo is performed using a handheld probe that accommodates the color sensor, filters, optics, and light source. The light source is composed of two high-intensity white LEDs, as well as a guiding light to illuminate the target during positioning of the probe.

Once the probe is in place, the LEDs flash at full power to illuminate the target area. Pigment levels are measured and recorded as melanin index values.

**Materials**

**A. Equipment:** DermaLab Skin Combo (Pigmentation Probe)

**Methods**

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 pigmentation probe was used to measure the erythema levels of the subject's volar forearms. Baseline pigmentation readings were taken on day one of the study.

Following initial measurements, all subjects were asked to apply 2 mg of each test material on their volar forearms. Measurements were taken immediately after application of test materials and then weekly for 4 weeks. The test material consisted of 2% **AC Dermal Respiratory Factor Advanced PF** 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

**AC Dermal Respiratory Factor Advance PF** showed reductions in erythema at a 2.0% concentration. Please note, each value is an average of three consecutive readings per test site.

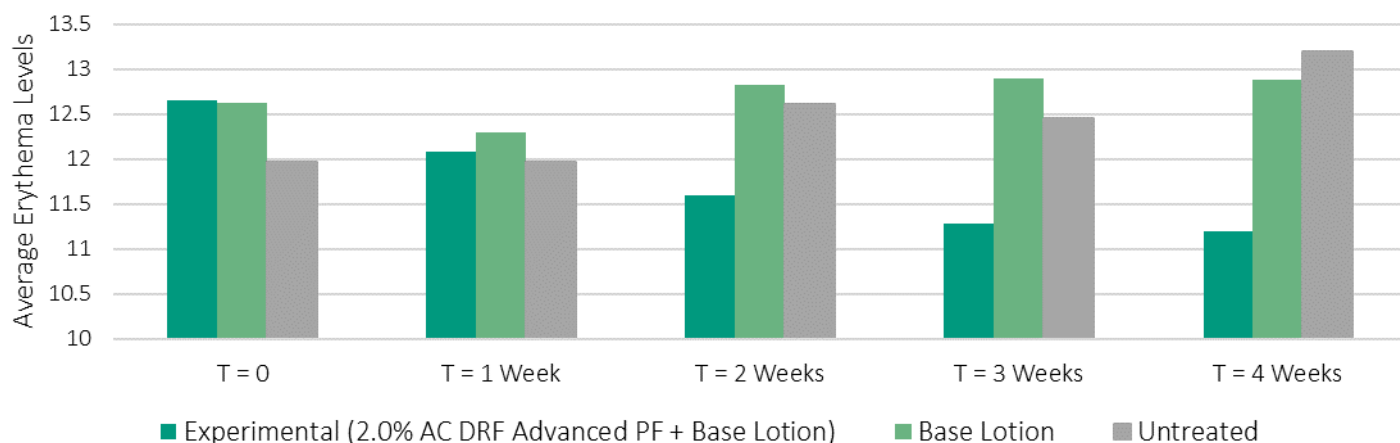
**Table 1.** Average Pigmentation Results per Individual Test Site

Averages	T = 0	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks
Experimental (2.0% AC DRF Advanced PF + Base Lotion)	13	12	12	11	11
Base Lotion	13	12	13	13	13
Untreated	12	12	13	12	13

**Table 2.** Percent Change Between Two Test Sites

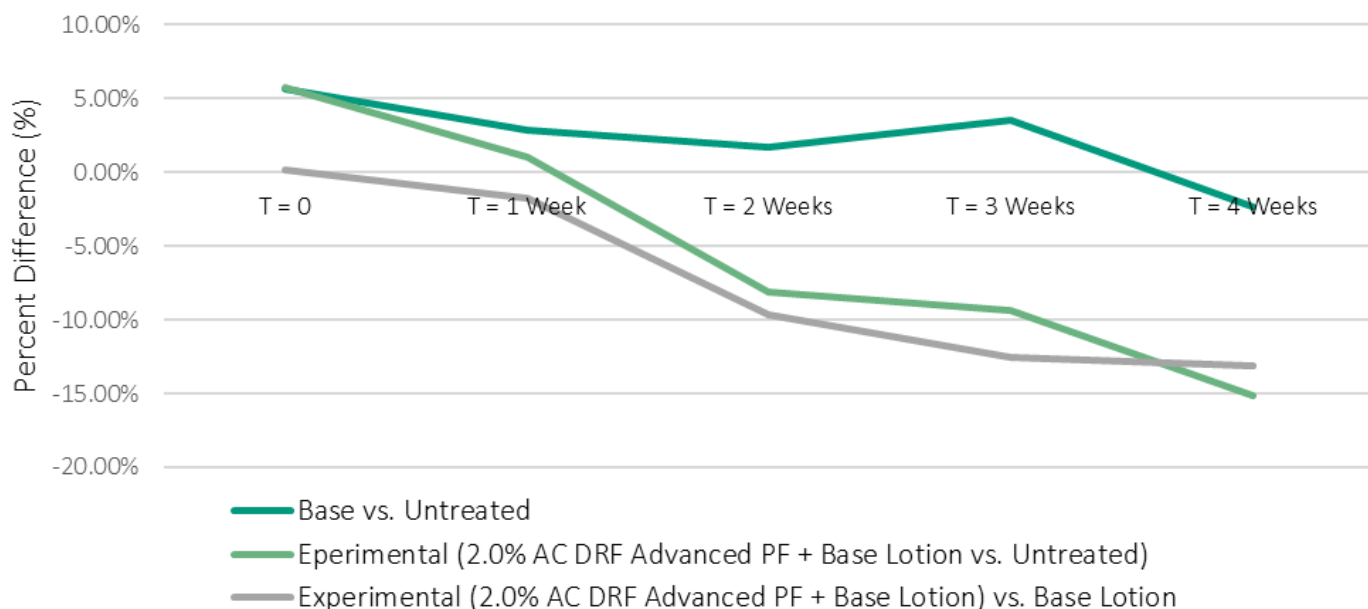
Percent (%) Change	T = 0	T = 1 Week	T = 2 Weeks	T = 3 Weeks	T = 4 Weeks
Base Lotion vs. Untreated	6	3	2	4	-2
Experimental (2.0% AC DRF Advanced PF + Base Lotion) vs. Untreated	6	1	-8	-9	-15
Experimental (2.0% AC DRF Advanced PF + Base Lotion) vs. Base Lotion	0	-2	-10	-13	-13

## Erythema Average Results for Individual Test Sites



**Figure 1.** Pigmentation Results for Individual Test Sites

## Erythema Comparative Data Between Two Test Sites



**Figure 2.** Pigmentation Results Compared in Percent Difference between Test Sites

## Discussion

As evidenced in a 4-week efficacy study of **AC Dermal Respiratory Factor Advanced PF** on skin, erythema values were decreased 5% more than the untreated test after one week. After 4 weeks, erythema values were decreased by 15% more than the untreated site. When compared to the base cream, **AC Dermal Respiratory Factor Advanced PF** decreased pigmentation 2% better after week one and after 4 weeks **AC Dermal Respiratory Factor** decreased pigmentation 13% more effectively than the base lotion alone. Results indicate that **AC Dermal Respiratory Factor Advanced PF** is capable of decreasing erythema when compared to both the untreated control as well as the base lotion.

**AC Dermal Respiratory Factor Advanced PF** has a lightening effect on skin's pigmentation when used at recommended use levels.