SPF Pigment Dispersion

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Tradename: ABS Acai Sterols EFA

Code: 10414

CAS #: 68990-51-2 & 60-33-3 & 112-80-1 & 463-40-1

Test Request Form #: 10104

Lot #: 9004500

Sponsor: *Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092*
Study Director: *Maureen Drumwright*
Principle Investigator: *Hannah Duckett*

Test Performed:
SPF Dispersion Assay

Introduction

Mineral sunscreens containing zinc oxide are known to leave a chalky or bluish finish on the skin which is undesirable to consumers. Pigment size and dispersion play a key role in a product's appearance on the skin. A product that has evenly dispersed, small pigments will appear more natural on the skin. By reducing the particle size, we can increase the transparency of the pigments which can lead to a better finish on the skin. The role of pigment dispersion in sunscreen formulations is, therefore, crucial to product appearance and consumer perception. A top performing product will consist of small pigment particles that do not agglomerate together and stay dispersed over time.

This SPF Dispersion assay was conducted to assess the ability of **ABS Acai Sterols EFA** to increase the dispersion properties of zinc oxide in sunscreen formulations both with and without the presence of a standard dispersing agent Polyhydroxystearic Acid (PHS).

Materials

A. **Equipment:** Light Microscope; Silverson High Shear Mixer; Canon EOS Rebel T3 Digital Camera
B. **Reagents:** Sunscreen Base (Table 1)
C. **Other:** Microscope slides

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Table 1. Sunscreen Base Ingredient List (*not all batches contained this ingredient)

INCI Name
Caprylic/Capric Triglyceride
Polyglyceryl-3 Polyricineoleate
Cera alba
Garcinia Indica Seed Butter
Polyhydroxystearic Acid*
Hydrogenated Polyisobutene
Zinc Oxide & Triethoxycaprylylsilane
Water
Sodium Chloride
Lactobacillus Ferment

Methods

The ability of **ABS Acai Sterols EFA** to disperse the pigment zinc oxide was evaluated using a multi-parameter approach. All formulas were produced according to the specific guidelines below to ensure pigment dispersion was not impacted by the manufacturing process.

Emulsions were formulated at 75°C and ingredients were added in four different phases using the same mix times. After cooling to room temperature, emulsions were tested immediately and again 24 hours after formulation. Emulsions were retested after 30 days to determine stability of the formulas.

Four different formulas were produced to help determine how **ABS Acai Sterols EFA** impacted sunscreen pigment dispersion both with and without the additional industry standard dispersing agent PHS:

1. 3.0% **ABS Acai Sterols EFA** + Sunscreen Base + PHS
2. Sunscreen Base + PHS
3. 3.0% **ABS Acai Sterols EFA** + Sunscreen Base
4. Sunscreen Base

30 mg of each formula was applied to a glass slide and examined under the light microscope utilizing a 40x objective. Five randomly chosen regions of each slide were evaluated to verify homogeneity of each dispersion. Microscopy images were taken of each region with a digital camera and were analyzed utilizing ImageJ analysis software (NIH). Pigment agglomerates were identified based on light intensity relative to the rest of the emulsion and the border of each agglomeration was determined. The total agglomeration area for each image was determined in ImageJ and is expressed in square millimeters (mm^2) by dividing the total area (exported in pixels) by a conversion factor of a given number of pixels per millimeter. An average total area was calculated from the five images and a t-test was run to verify significance. This method observes both soft and hard agglomerates. The average total area is useful because it demonstrates the total amount of visible agglomerates present in each image. Ideally a well dispersed product will have few to no large or visible agglomerates and will therefore have a lower average total area.

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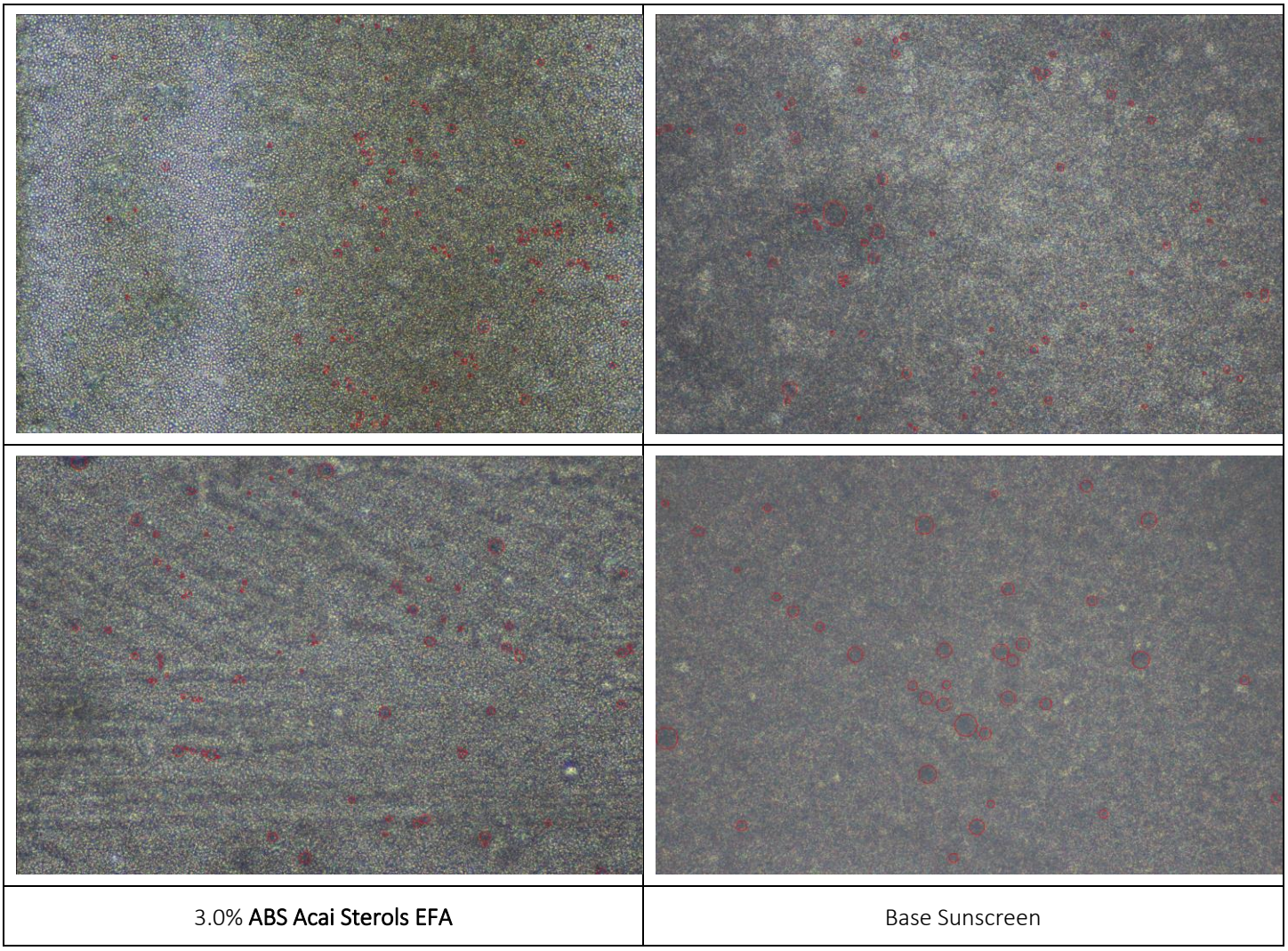
Results

The data obtained from this study met criteria for a valid assay and the controls performed as anticipated. **ABS Acai Sterols EFA** at a concentration of 3.0% was able to improve pigment dispersion in a sunscreen base.



3.0% **ABS Acai Sterols EFA**	Base Sunscreen

Figure 1. Initial (T=0 Hours) Images of Each Material at 40x Objective, (top) with PHS and (bottom) without PHS. Agglomerates Indicated by Red Circles

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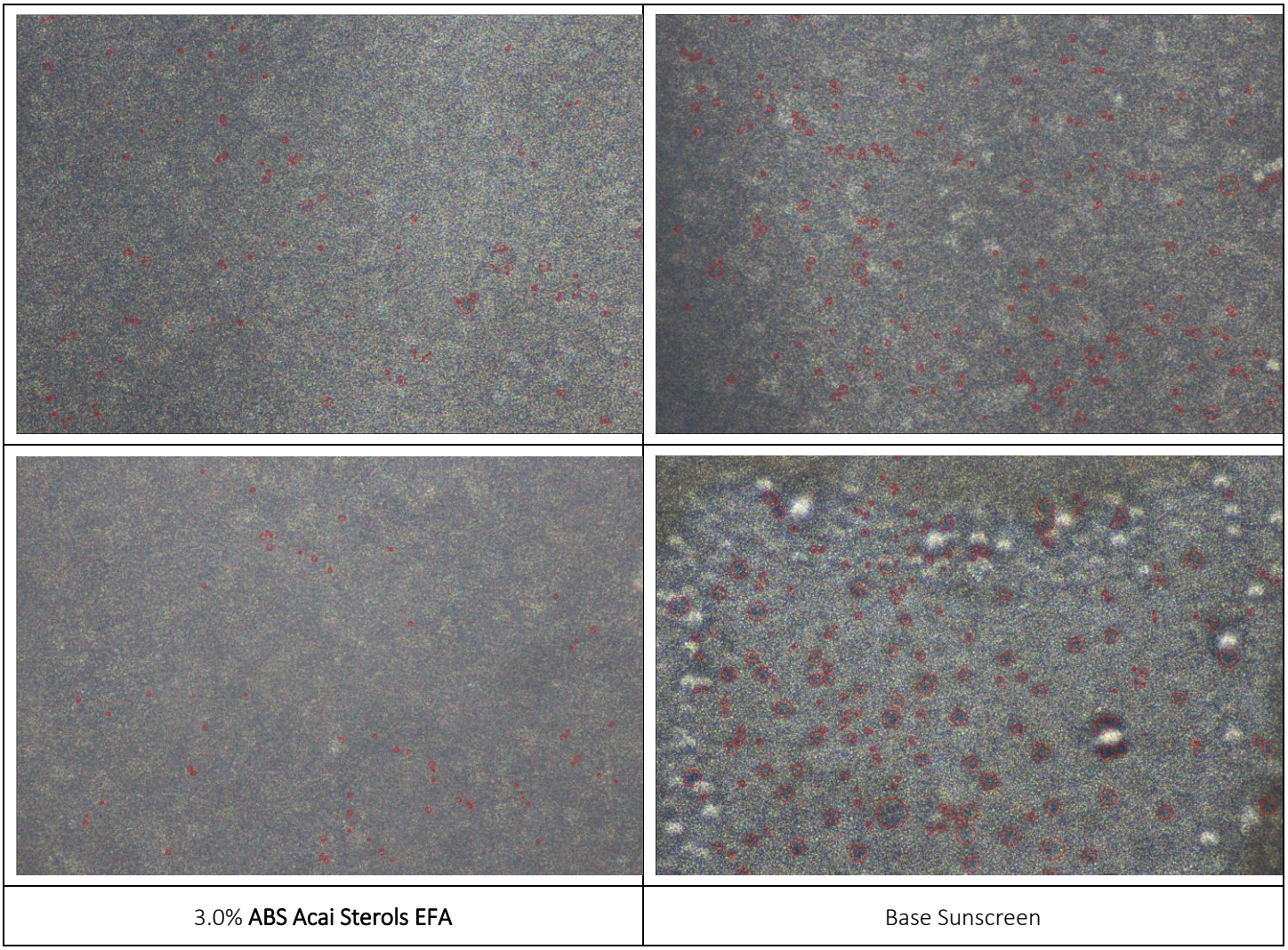

3.0% **ABS Acai Sterols EFA**	Base Sunscreen

Figure 2. Final (T=24 Hours) Images of Each Material at 40x Objective, (top) with PHS and (bottom) without PHS. Agglomerates Indicated by Red Circles

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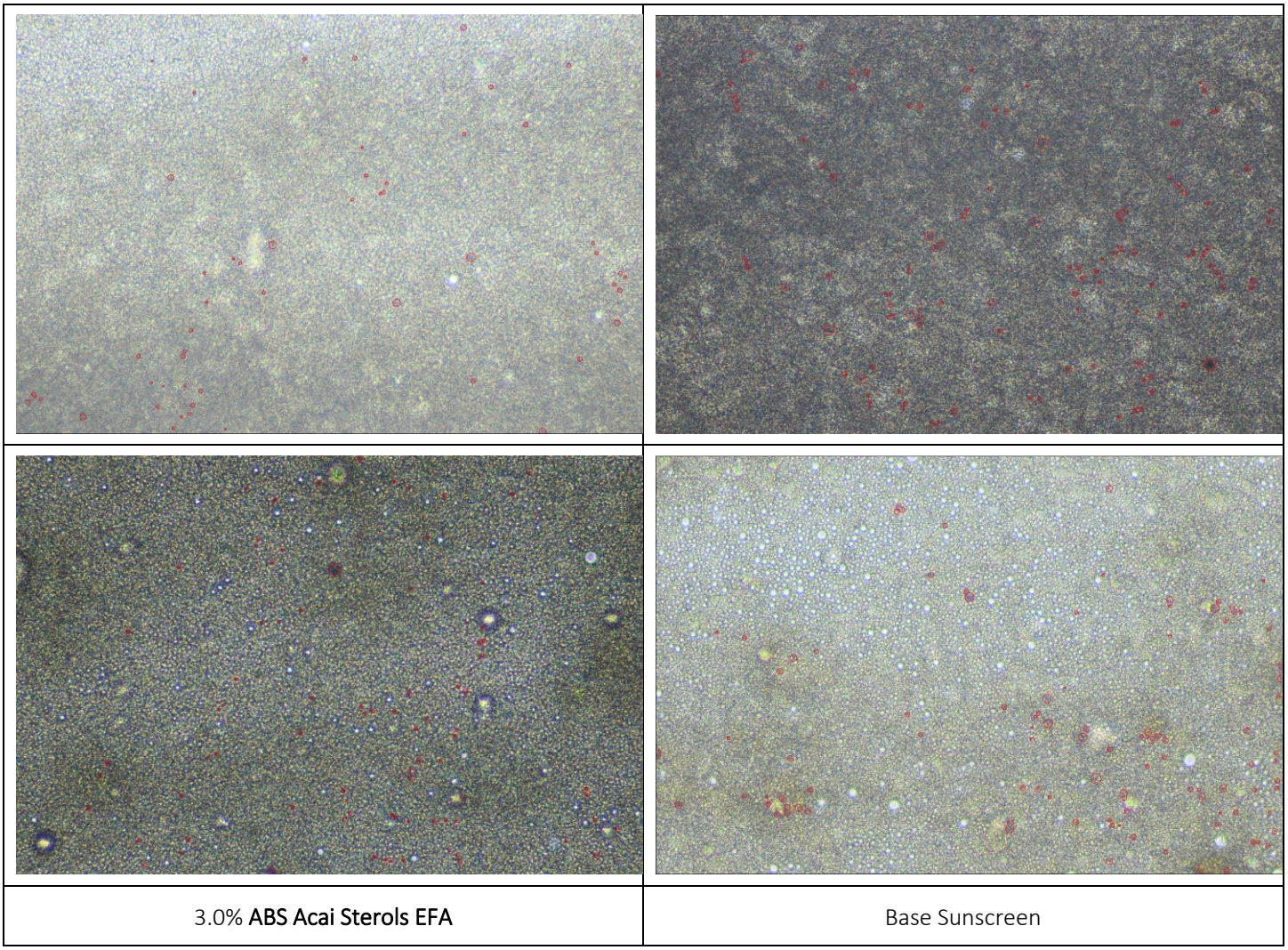

3.0% **ABS Acai Sterols EFA**	Base Sunscreen

Figure 3. Stability (T=30 Days) Images of Each Material at 40x Objective, (top) with PHS and (bottom) without PHS. Agglomerates Indicated by Red Circles

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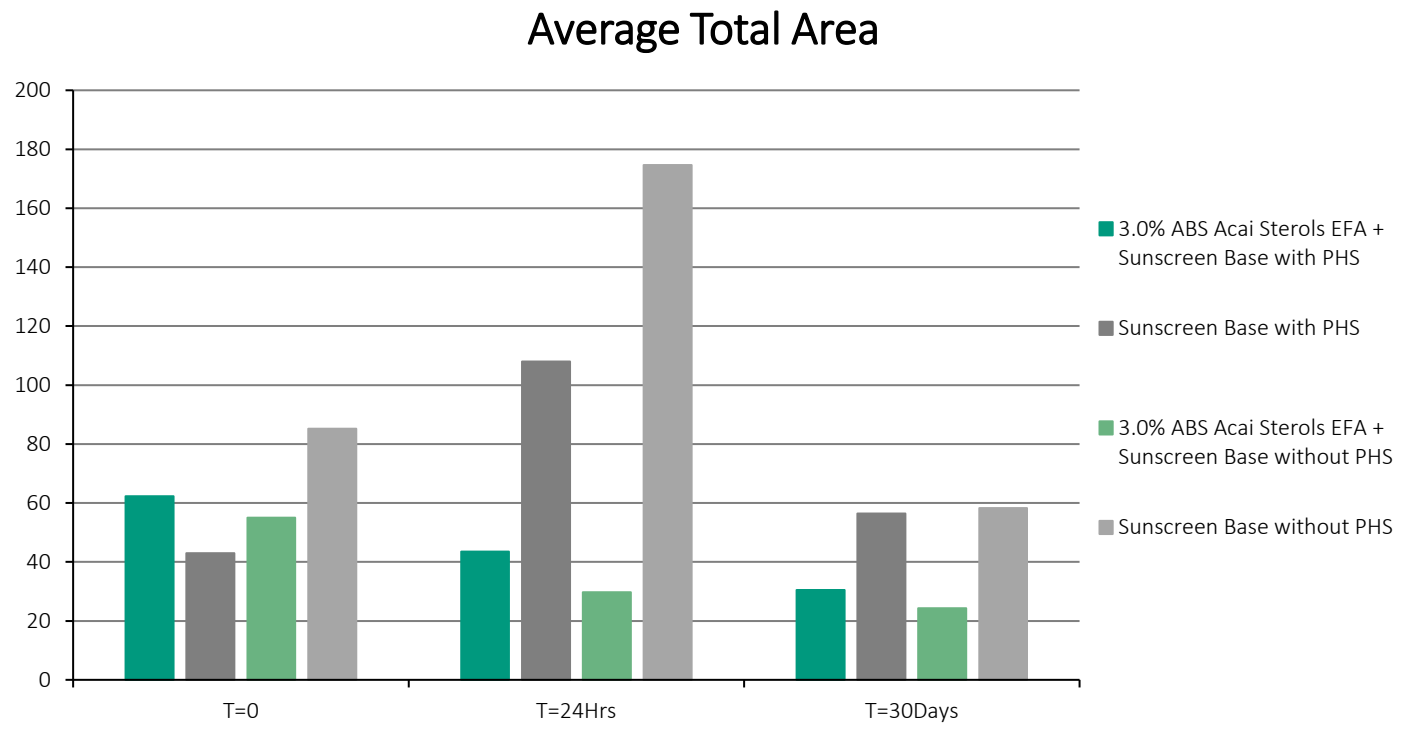

Figure 3. Average Total Area of Pigment Agglomerates (mm^2) of Each Material at All Time Points

Table 2. Comparative Agglomerate Area between Test Materials at Each Time Point

Percent Difference (%)	T = 0 Hours	T = 24 Hours	T = 30 Days
3.0% **ABS Acai Sterols EFA** + Sunscreen Base with PHS vs Sunscreen Base with PHS	36.58	85.10	59.78
3.0% **ABS Acai Sterols EFA** + Sunscreen Base without PHS vs Sunscreen Base without PHS	43.13	141.92	82.40
3.0% **ABS Acai Sterols EFA** + Sunscreen Base with PHS vs 3.0% **ABS Acai Sterols EFA** + Sunscreen Base without PHS	12.45	37.81	22.55
Sunscreen Base with PHS vs Sunscreen Base without PHS	65.81	47.20	3.29
3.0% **ABS Acai Sterols EFA** + Sunscreen Base without PHS vs Sunscreen Base with PHS	24.41	133.77	79.64

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Table 3. T-test Analysis of the Average Total Area Difference (%) Between 3.0% **ABS Acai Sterols EFA** without PHS and Sunscreen Base with PHS at T = 0 (n=5, α=0.05, df=8)

	3.0% **ABS Acai Sterols EFA** without PHS	**Sunscreen Base with PHS**
Mean	54.97	43.01
Variance	435.83	376.78
t Stat	-0.94	
P(T<=t) two-tail	0.38	
t Critical two-tail	2.31	

Table 4. T-test Analysis of the Average Total Area Difference (%) Between 3.0% **ABS Acai Sterols EFA** without PHS and 3.0% **ABS Acai Sterols EFA** with PHS at T = 24 Hours (n=5, α=0.05, df=7)

	3.0% **ABS Acai Sterols EFA** without PHS	3.0% **ABS Acai Sterols EFA** with PHS
Mean	29.68	43.51
Variance	48.83	118.82
t Stat	2.39	
P(T<=t) two-tail	0.048	
t Critical two-tail	2.36	

Table 5. T-test Analysis of the Average Total Area Difference (%) Between 3.0% **ABS Acai Sterols EFA** without PHS and Sunscreen Base with PHS at T = 24 Hours (n=5, α=0.05, df=4)

	3.0% **ABS Acai Sterols EFA** without PHS	**Sunscreen Base with PHS**
Mean	29.67	107.98
Variance	48.83	884.24
t Stat	5.73	
P(T<=t) two-tail	0.0046	
t Critical two-tail	2.78	

Table 6. T-test Analysis of the Average Total Area Difference (%) Between 3.0% **ABS Acai Sterols EFA** with PHS and Sunscreen Base with PHS at T = 24 Hours (n=5, α=0.05, df=5)

	3.0% **ABS Acai Sterols EFA** with PHS	**Sunscreen Base with PHS**
Mean	43.51	107.98
Variance	118.81	884.24
t Stat	4.55	
P(T<=t) two-tail	0.0061	
t Critical two-tail	2.57	

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Table 7. T-test Analysis of the Average Total Area Difference (%) Between 3.0% **ABS Acai Sterols EFA** without PHS and Sunscreen Base with PHS at T = 30 Days (n=5, α=0.05, df=8)

	3.0% **ABS Acai Sterols EFA** without PHS	**Sunscreen Base with PHS**
Mean	24.27	56.39
Variance	34.66	48.29
t Stat	7.89	
P(T<=t) two-tail	4.84E-05	
t Critical two-tail	2.31	

Table 8. T-test Analysis of the Average Total Area Difference (%) Between 3.0% **ABS Acai Sterols EFA** without PHS and Sunscreen Base without PHS at T = 30 Days (n=5, α=0.05, df=5)

	3.0% **ABS Acai Sterols EFA** without PHS	**Sunscreen Base without PHS**
Mean	24.27	58.28
Variance	34.66	548.20
t Stat	3.15	
P(T<=t) two-tail	0.025	
t Critical two-tail	2.57	

Table 9. T-test Analysis of the Average Total Area Difference (%) Between 3.0% **ABS Acai Sterols EFA** with PHS and Sunscreen Base with PHS at T = 30 Days (n=5, α=0.05, df=7)

	3.0% **ABS Acai Sterols EFA** with PHS	**Sunscreen Base with PHS**
Mean	30.44	56.39
Variance	82.78	48.29
t Stat	5.07	
P(T<=t) two-tail	0.0014	
t Critical two-tail	2.36	

Discussion

The data obtained from this study indicates that **ABS Acai Sterols EFA (10414)** was able to improve pigment dispersion in sunscreen formulations.

The dispersions containing **ABS Acai Sterols EFA** had fewer visible pigment agglomerates than that of the bases alone. As demonstrated in Figure 3, immediately after production the experimental material without PHS had an average total pigment area of 54.97mm^2 while the base sunscreen with PHS had an average total area of 43.01mm^2. As demonstrated in tables 2 & 3, the 24.41% difference between the two was shown to be insignificant ($p>0.05$). Additionally, the base without PHS present had a larger average total area than all the formulations of 85.19mm^2 (Figure 3). The experimental formula without the dispersing agent (PHS) present provided comparable results to that of the base containing PHS indicating that when **ABS Acai Sterols EFA** is present, it has the ability to boost pigment dispersion and can actually replace PHS in a formula.

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ABS Acai Sterols EFA, both with and without PHS, outperformed the two base formulas 24 hours post-production. The experimental formula without PHS performed the best and had a lower total area by 37.81% (p=0.048), 113.77% (p=0.0046), and 141.92% when compared to the experimental with PHS, the base containing PHS, and the base without PHS, respectively (Tables 2, 4 & 5). The experimental formula with PHS present also outperformed the base with PHS by 85.11% (p=0.0061) at this time point (Tables 2 & 6). After 24 hours, it is evident that **ABS Acai Sterols EFA** can provide better stability of SPF pigments both with and without the presence of a standard dispersing agent.

Analysis after a 30-day stability period further demonstrated that **ABS Acai Sterols EFA** is capable of replacing and outperforming the standard dispersing agent PHS. The experimental formula without PHS present still outperformed all other formulations with a lower total area by 22.55%, 79.64% (p=4.84E-05), and 82.40% (p=0.025) when compared to the experimental containing PHS, the base with PHS and the base without PHS, respectively (Tables 2, 7 & 8). Additionally, the experimental with PHS had a lower total area by 59.78% (p=0.0014) when compared to the base with PHS present (Tables 2 & 9). **ABS Acai Sterols EFA** is, therefore, capable of providing long term zinc oxide pigment stability in SPF formulations.

With the present study, it can be concluded that at normal use concentrations **ABS Acai Sterols EFA** can be used to improve zinc oxide pigment dispersion in sunscreen products.