

# ABS Pomegranate Sterols Efficacy Data

Code:10247INCI Name:Punica Granatum SterolsCAS #:949109-75-5EINECS #:N/A

Type of Study	Results
Sensory Assessment of Formulations	A shampoo containing <b>ABS Pomegranate Sterols</b> provided rich and creamy foam, and it gave a smooth, moist, and supple result, compared to a shampoo containing Lanolin which gave poor foam and made the hair feel "squeaky" while rinsing. The conditioning treatment containing <b>ABS</b> <b>Pomegranate Sterols</b> also provided a silky smooth, moist, and supple feeling, while Lanolin made the hair feel heavy. <b>ABS Pomegranate</b> <b>Sterols</b> in the hair cream and wax had good affinity, gave moisture, smoothness, gloss, and a natural styling ability. <b>ABS Pomegranate</b> <b>Sterols</b> is ideal as a moisturizer and hydrator in hair products.
Moisturization Assay	The results indicate that <b>ABS Pomegranate Sterols</b> is an effective hydrating ingredient. After 21 days, 5.0% <b>ABS Pomegranate Sterols</b> was improved hydration by 24.0% compared to baseline hydration values. The comparison to the control lotion showed that after 21 days, test sites treated with <b>ABS Pomegranate Sterols</b> had a 19.0% improvement in hydration.
Hydration Potential Assay	The results indicate that <b>ABS Pomegranate Sterols</b> is an excellent all natural and botanical alternative to Lanolin as it is capable of holding 200% of its weight in water. Data analysis also reveals that compared to Avocado Sterols, Petrolatum, and Jojoba Oil, <b>ABS Pomegranate Sterols</b> exhibited superior hydration potential with respective improvements in water holding capacity of 60%, 900% and 3900%.
Coefficient of Permeability	A higher value for the Coefficient of Permeability represents more liquid was able to seep through into the solution, and thus a lower barrier function. <b>ABS Pomegranate Sterols</b> has a lower Coefficient of Permeability than Dimethicone, Triethylhexanoin, Mineral Oil, and Lanolin, meaning <b>ABS Pomegranate Sterols</b> is better for protecting against Transepidermal Water Loss.

Version#3/09.14.16



High Resolution Ultrasound Skin Imaging Assay

As evidenced in a 4 week efficacy study, **ABS Pomegranate Sterols** improved skin density by 29.20% after 24 hours and by 44.19% after 4 weeks when compared to the untreated control. When compared to the base cream **ABS Pomegranate Sterols** improved skin density by 32.23% after 24 hours and after 4 weeks **ABS Pomegranate Sterols** improved density by 32.20%. Results indicate that **ABS Pomegranate Sterols** is capable of improving skin density when compared to both the untreated control as well as the base lotion.

Version#3/09.14.16



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#### Abstract

**ABS Pomegranate Sterols** is an oligomer type Phytosterol ester in a paste that melts at ~38°C. The feature characteristics of **ABS Pomegranate Sterols** are as follows:

<u>Hydration Potential</u> – Promotes excellent emollient and moisturized sensation so that it maintains healthy hair and repairs damaged hair.

High Refractive Index – Excellent shine and gloss.

Excellent Oxidation Stability – Durable in storage.

High Pigment Dispersing Ability – Great in skincare and makeup products.

#### **Materials and Methods**

#### **Formulations:**

We created the following formulations to test the feature characteristics of ABS Pomegranate Sterols:

<u>Shampoo</u> – Gives creamy and rich foam to shampoo. Provides smooth and supple feel to hair. Also useful in 2-in-1 Shampoo.

Conditioning Treatment – Restores smoothness, moisture, and suppleness to hair.

<u>Cream</u> – Affinitive to hair and gives shine, smoothness, and moisture without a sticky feeling.

<u>Wax</u> – Affinitive to hair and gives smoothness and moisture, and provides a natural styling ability without a sticky feeling.

#### Sensory Assessment:

Volunteers were asked to use each of the aforementioned formulations once a day for 5 days (not in conjunction), and their sensory assessments were evaluated on a scale of 1-10 (10 being the most desirable quality, 1 being the least desirable quality).

#### Results

<u>Shampoo</u>

Washing and Rinsing	ABS Pomegranate Lanolin		After Drying	ABS Pomegranate Lanolin		
	Sterols 1%	1%		Sterols 1%	1%	
Smoothness	7.1	4.6	Smoothness	7.2	2.9	
<b>Rich and Creamy Foam</b>	7.5	6.0	Moisture	7.1	3.3	
Suppleness	7.1	5.1	Suppleness	6.4	4.7	
Residual Feeling	7.0	4.9	Manage-ability	<i>y</i> 5.3	4.5	

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# Sensory Assessment of Formulations ABS Pomegranate Sterols

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#### Conditioning Treatment

Washing and	<b>ABS Pomegranate</b>	Lanolin	After Drying	ABS Pomegranate	Lanolin
Rinsing	Sterols 1%	1%		Sterols 1%	1%
Smoothness	9.5	2.5	Smoothness	7.9	2.6
Richness	7.8	3.1	Richness	6.9	4.0
Suppleness	8.0	2.9	Suppleness	6.2	4.7
<b>Residual Feeling</b>	9.4	2.2	Manage-ability	7.6	4.9
Moisture	7.6	3.0	Moisture	7.7	4.8

<u>Cream</u>

	<b>ABS Pomegranate</b>	Lanolin
	Sterols 2%	2%
Smoothness	7.6	2.9
Affinity	7.4	4.3
Moisture	7.8	4.0
Lightness	7.1	4.4

Wax

	<b>ABS Pomegranate</b>	Lanolin	
	Sterols 4%	4%	
Affinity	7.4	2.7	
Adhesiveness	7.8	4.8	
Styling	7.8	2.6	
Lightness	6.9	3.0	
Smoothness	8.0	4.5	
Moisture	8.1	4.1	
Stickiness	7.0	2.8	

#### Discussion

According to the sensory assessment by the volunteers, the shampoo containing **ABS Pomegranate Sterols** provided rich and creamy foam, and it gave a smooth, moist, and supple result, while the shampoo containing Lanolin gave poor foam and made the hair feel "squeaky" while rinsing. The conditioning treatment containing **ABS Pomegranate Sterols** also provided a silky smooth, moist, and supple feeling, while Lanolin made the hair feel heavy. **ABS Pomegranate Sterols** in the hair cream and wax had good affinity, gave moisture, smoothness, gloss, and a natural styling ability, while Lanolin again created a heavy feeling. Thus we feel this provides sufficient evidence by consumer opinion that **ABS Pomegranate Sterols** is a better substitute than Lanolin as a moisturizer and hydrator in hair products, as it leaves the consumer with a healthy, smooth feeling.

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## ABS Pomegranate Sterols (10247) Moisturization Study

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## Abstract

Observed changes in epidermal hydration are often quantified by measuring changes in electrical conductance of the stratum corneum via impedance measurements. A DPM 9003 NOVA Impedance meter was used to observe improvements in moisturization following treatment with ABS Pomegranate Sterols.

## **Materials and Methods**

A panel of 10 male and female subjects between the ages of 22 and 41 was assembled to determine the moisturizing improvements of ABS Pomegranate Sterols over the course of a 28-day study. Subjects participated in a 3 day dry-down phase before the on set of the study. 5% ABS Pomegranate Sterols (lot: SNO90622-1) was incorporated into a lotion which was used as the test vehicle, the same lotion without ABS Pomegranate Sterols was used as the control. Both the lotion containing ABS Pomegranate Sterols and unloaded vehicle were applied to randomized 2cm<sup>2</sup> patches on the subjects' left or right volar forearm twice daily for the duration of the study. On day 0, moisturization measurements were taken of the subjects forearm prior to applying either lotion. Repeat measurements were then taken weekly until the study was completed. Results for both the control and test treatment were compared to the initial impedance values that were taken on day 0.



## Results

Figure 1. Mean impedance measurement results for lotion containing 5% ABS Pomegranate Sterols compared to control lotion and untreated site.

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Figure 2. Percent Improvement in hydration properties for ABS Pomegranate Sterols compared to control lotion and untreated site.

	ABS Pomegranate Sterols	Untreated Site
Mean	125.5	99.3333
Variance	854.3605927	33.3821729
Observations	10	10
Pearson Correlation	0.29897169	
Hypothesized Mean Difference	0	
df	9	
t Stat	2.95003537	
P(T<=t) one-tail	0.008109999	
t Critical one-tail	1.833112923	
P(T<=t) two-tail	0.016219998	
t Critical two-tail	2.262157158	

Table 1. Statistical analysis comparing results for ABS Pomegranate Sterols to the results for the Untreated Site.

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# ABS Pomegranate Sterols (10247) Moisturization Study

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	ABS Pomegranate Sterols	Control Lotion
Mean	125.5	105.7333
Variance	854.3605927	36.36363468
Observations	10	10
Pearson Correlation	0.339430256	
Hypothesized Mean Difference	0	
df	9	
t Stat	2.251063735	
P(T<=t) one-tail	0.025457347	
t Critical one-tail	1.833112923	
P(T<=t) two-tail	0.050914695	
t Critical two-tail	2.262157158	

Table 2. Statistical analysis comparing results for ABS Pomegranate Sterols to results for the control lotion.

### Discussion

The results indicate that ABS Pomegranate Sterols is an effective hydrating ingredient. After 21 days, 5% ABS Pomegranate Sterols was observed to improve hydration by 24% compared to baseline hydration values. The comparison to the control lotion showed that after 21 days, test sites treated with ABS Pomegranate Sterols had a 19% improvement in hydration. Data analysis confirms that the results are statistically significant. These findings suggest that ABS Pomegranate Sterols is useful in topical applications which are intended to moisturize the skin.

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# Hydration Potential ABS Pomegranate Sterols

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#### Abstract

The purpose of this study was to determine the hydration potential of **ABS Pomegranate Sterols** in comparison to some of its natural, synthetic, and animal-derived competitors.

#### **Materials and Methods**

Hydration Potential was measured according to the British Pharmacopoeia (BP) water absorption capacity method. Following this procedure, sample materials were placed separately into a mortar. Water was then incrementally added to the sample and mixed using a pestle. Samples were considered to be saturated when no more water can be mixed into the emulsion. The point at which a sample is fully saturated is referred to as the terminal point. The water holding capacity was then calculated by dividing the weight of the sample after the terminal point has be reached by the initial sample weight and multiplying by 100 as is indicated in the below equation.

Water Holding Capacity (%) = (Weight of sample after terminal point is reached/Weight of Initial Sample) x 100

**Hydration Potential** 



#### Results

#### Discussion

The results indicate that ABS Pomegranate Sterols is an excellent all natural and botanical alternative to Lanolin as it is capable of holding 200% of its weight in water. Data analysis also reveals that compared to Avocado Sterols, Petrolatum, and Jojoba Oil, ABS Pomegranate Sterols exhibited superior hydration potential with respective improvements in water holding capacity of 60%, 900% and 3900%. These findings confirm that ABS Pomegranate Sterols is useful in topical applications to effectively deliver moisture to the skin.

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# **Coefficient of Permeability ABS Pomegranate Sterols**

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#### Abstract

The purpose of this study was to determine the ability of **ABS Pomegranate Sterols** to increase barrier function and reduce the coefficient of permeability of hydration through a membrane.

#### **Materials and Methods**

The sample oil and Mineral Oil 70 were mixed together in a 1:1 ratio. This mixture was applied to filter paper, which was then placed on top of a measurement cup containing CaCl2 solution. These were allowed to stand for 24 hours at 25°C with 95% RH, and the weight of the moisture that permeated through the filter paper and into the solution was measured as increased weight. The Coefficient of Permeability was shown in percentage by comparing increase in weight to a control where no oils were applied.

#### Results



### **Coefficient of Permeability**

Figure 1. Coefficient of Permeability Measurements

#### Discussion

A higher number for the Coefficient of Permeability means that more liquid was able to seep through into the solution, and thus a lower barrier function. According to figure 1, **ABS Pomegranate Sterols** has a lower Coefficient of Permeability than Dimethicone, Triethylhexanoin, Mineral Oil, and Lanolin, which means that **ABS Pomegranate Sterols** provides better barrier function than all of these products, as it does not allow for moisture loss.

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Tradename: ABS Pomegranate Sterols

**Code:** 10247

CAS #: 949109-75-5

Test Request Form #: 526

Lot #: 27174

**Sponsor:** Active Concepts, LLC; 107 Technology Drive Lincolnton, NC 28092 **Study Director:** Erica Segura **Principle Investigator:** Meghan Darley

<u>Test Performed:</u> 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 **ABS Pomegranate Sterols.** 10 M/F subjects between the ages of 23-45 participated in the study. Results 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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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. Baseline elasticity 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 2.0% **ABS Pomegranate Sterols** 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

**ABS Pomegranate Sterols** 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	47	66	67	50	61
Untreated Control	53	54	50	42	45
Control	47	44	45	42	41
Subject 2-Test	97	65	100	100	77
Untreated Control Base Lotion	51	60	65	65	68
Control	65	69	89	86	75
Subject 3-Test	100	99	86	97	0
Untreated Control Base Lotion	71	67	68	64	0
Control	70	59	62	79	0
Subject 4-Test	86	78	92	95	92
Untreated Control Base Lotion	72	59	54	62	60
Control	50	70	74	52	67
Subject 5-Test	71	86	85	88	84
Untreated Control Base Lotion	46	53	43	50	58
Control	47	53	42	59	59

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# **High Resolution Ultrasound Skin Imaging Assay**

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	t = 24	1 week	2 weeks	3 weeks	4 weeks
Subject 6-Test	59	77	81	82	0
Untreated Control	40	46	56	38	0
Base Lotion					
Control	44	59	46	43	0
Subject 7-Test	61	64	64	72	60
Untreated Control	60	60	58	49	45
Base Lotion					
Control	63	51	58	65	61
Subject 8-Test	0	78	85	81	86
Untreated Control	0	51	50	52	42
Base Lotion				. –	
Control	0	58	48	45	47
Subject 9-Test	72	72	75	50	67
Untropted Control	72	12	10	20	40
Base Lotion	55	43	49	29	40
Control	54	50	55	34	52
Control	04	00	00	04	02
Subject 10-Test	84	96	86	80	93
Untreated Control	76	69	74	68	72
Base Lotion					
Control	72	70	66	69	67
# of Subjects	9	10	10	10	8

#### **Results of Group:**

	t = 24	1 week	2 week	3 week	4 week
Experimental (2.0% ABS Pomegranate Sterols in Base Lotion)	75.2	78.1	82.1	80.4	77.5
Untreated	58.2	56.2	56.7	51.9	53.8
Base Lotion Control	56.9	58.3	58.5	57.4	58.6
	t = 24	1 week	2 week	3 week	4 week
Experimental vs. Untreated Control	29.20%	38.97%	44.80%	54.91%	44.19%
Base Lotion vs. Untreated Control	-2.29%	3.74%	3.17%	10.60%	9.07%
Experimental vs. Base Lotion	32.23%	33.96%	40.34%	40.07%	32.20%

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Figure 1: High Resolution Ultrasound Skin Imaging Results

## Discussion

As evidenced in a 4 week efficacy study of **ABS Pomegranate Sterols** on skin, skin density was improved by 29.20% after 24 hours and by 44.19% after 4 weeks when compared to the untreated control. When compared to the base cream **ABS Pomegranate Sterols** improved skin density by 32.23% after 24 hours and after 4 weeks **ABS Pomegranate Sterols** improved density by 32.20%. Results indicate that **ABS Pomegranate Sterols** is capable of improving skin density when compared to both the untreated control as well as the base lotion.

ABS Pomegranate Sterols has a strong positive effect on skin's density when used at recommended use levels.

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