

# Long-term Efficacy and Tolerance of an Acne Clarifying Set for Cleansing Acneic Skin

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## **INTRODUCTION**

The delicate, compromised skin associated with specific skin conditions presents cleansing challenges. Removal of dirt, oil, and bacteria without harming the function of the skin barrier are important when cleansing the skin. Pacific Bioscience Laboratories has developed an acne clarifying set (cleansing regimen) containing a sonic skin care brush (with an acne brush head) and a salicylic acid acne cleanser (2% salicylic acid). The salicylic acid cleanser contains USA Food and Drug Administration (FDA) approved over-the-counter (OTC) ingredients for the treatment of acne. This cleansing regimen is designed for daily cleansing of delicate, compromised acneic skin.

## **OBJECTIVES**

To evaluate the safety and efficacy of an acne cleansing regimen.

## MATERIALS AND METHODS

50 subjects between the ages of 18 and 60, with mild to moderate acne, using prescription acne medications for a minimum of 6 months were enrolled in this 12-week study. The study consisted of two parts. The subjects were instructed to use the cleansing regimen whenever they cleansed their skin (morning and/or bedtime), not exceeding twice per day.

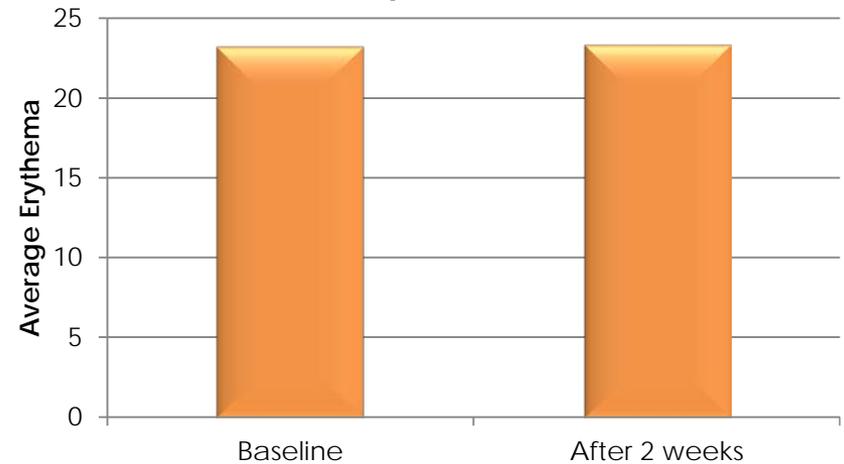
**Part I** (safety) evaluated safety in a subgroup of 38 subjects by assessing the skin's sensitivity and reaction to use of the cleansing regimen. Safety was assessed before and after 2 weeks of product use via investigator global acne assessments (5 point ranking scale), photographs, and measurements of Trans Epidermal Water Loss (TEWL), Erythema, and Hydration (Corneometry).

In **Part II** (efficacy and safety) of the study, the subjects continued to use the cleansing regimen at home for an additional 10 weeks (n=50). This part evaluated long-term safety and efficacy through assessments of the skin by the investigator (global acne assessments, 5 point ranking scale), photographs, and user perception (a series of questionnaires).

## RESULTS

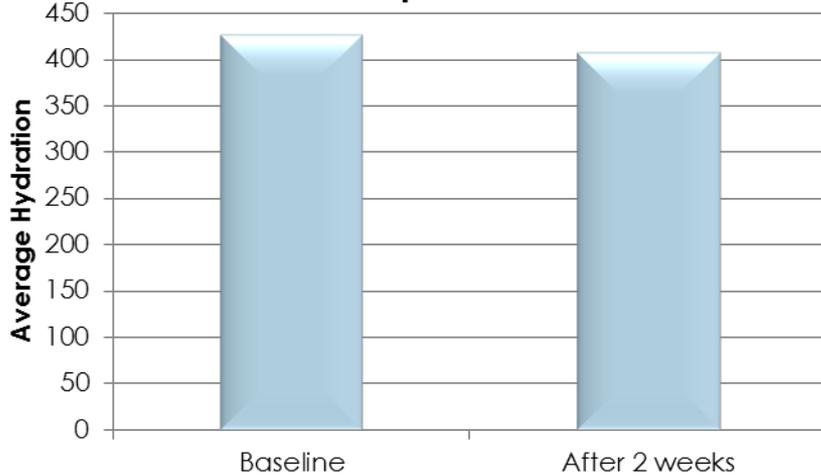
**Part I:** After 2 weeks of product use- A) TEWL measurements remained in the range for healthy skin (10-15 g/m<sup>2</sup>/h), indicating that there was no disruption to skin barrier and that the acne cleansing regimen is gentle for daily use. B) There was no statistically significant change (p=0.77) in erythema, indicating that the cleansing regimen did not cause any redness or irritation. C) There was no statistically significant change (p=0.28) in hydration, indicating that the cleansing regimen is not drying to the skin.

**Erythema\* at baseline and after 2 weeks of product use**



\*Average of both the cheeks

## Hydration\* at baseline and after 2 weeks of product use

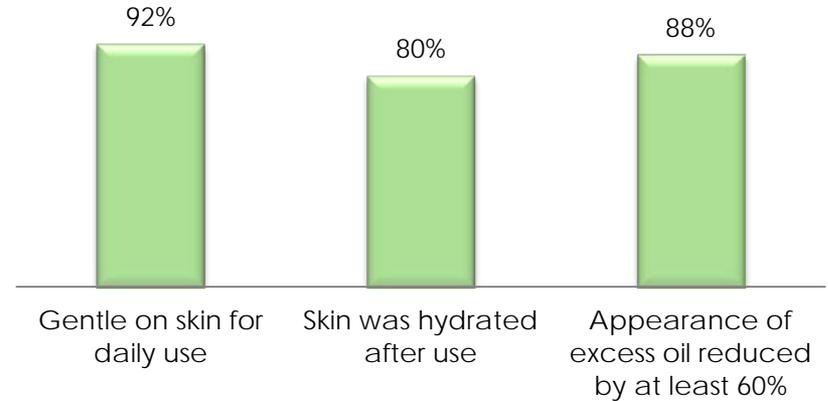


\*Average of both the cheeks

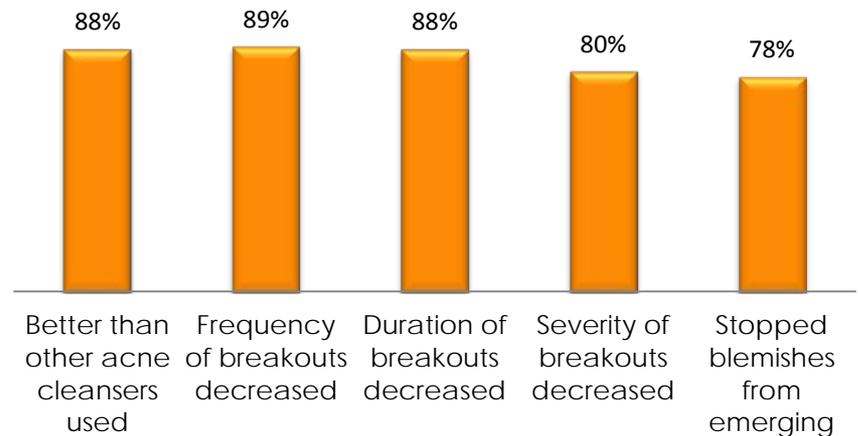
## RESULTS

Part II: After 12 weeks of product use, the questionnaire data revealed that 92% of participants perceived the cleanser to be gentle on their skin for daily use, 80% felt their skin was hydrated after use, 88% saw a reduction in the appearance of excess oil by at least 60%. Subjects reported decreased frequency, duration and severity of their breakouts (89%, 88%, 80%; respectively),

## Questionnaire data after using the acne clarifying regimen for 12 weeks



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A Wilcoxon signed-rank test of the investigator acne assessment scores (5 point ranking scale, 0=none and 4=Severe) showed that there was a statistically significant improvement in global acne assessment ranks at 2 weeks ( $p=0.000$ ), 6 weeks ( $p=0.000$ ), 12 weeks ( $p=0.000$ ) when compared to baseline.



a



b



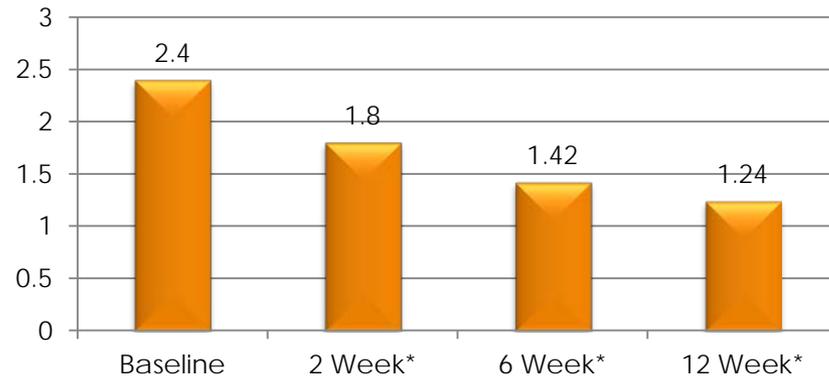
a



b

**Figure 1.**  
Subjects at baseline (a) and 12 weeks (b).

## Average Score Per Study Visit- Global Acne Assessment Scores



\*Significantly lower than baseline

## CONCLUSIONS

The acne clarifying set is safe and effective for daily cleansing of acneic skin.

## REFERENCES

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