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## ***Alpha-gel layered facial cleanser: A natural origin combination of polyglycerol surfactant and amino acid surfactant achieves ultra-gentle efficacy***

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### **1. Introduction**

In recent years, the prevalence of individuals with sensitive skin has exhibited a consistent upward trend [1]. Consumer awareness regarding skin sensitivity has been increasing, which gives rise to a significant demand for ultra-gentle cosmetics that can cater to the delicate needs of sensitive skin. Among the various cosmetic products, facial cleansers occupy a pivotal position in skincare, as they represent the initial step in daily skincare routines.

Conventional facial cleansers have historically employed surfactants, such as soap and sulfates, to achieve their cleansing objectives [2]. However, a mounting body of research and consumer feedback has exposed a significant drawback of such surfactants: their potential to induce skin irritation and compromise the integrity of the skin barrier [3]. When applied to the skin, conventional surfactants have the capacity to remove not only unwanted dirt and oils but also the skin's natural moisturizing factors and lipids. Consequently, the integument may become desiccated, pruritic, and more vulnerable to external irritants and allergens, which is a salient concern for individuals with sensitive skin types [3,4].

In light of these considerations, there has been an escalation in the pursuit of alternative formulation technologies capable of delivering efficacious cleansing while upholding epidermal compatibility. Alpha-gel technology has emerged as a promising yet relatively under-researched approach in the realm of structured cosmetic formulations [5]. Alpha-gel represents a distinctive class of systems, distinguished by their unique microstructures and rheological properties [6]. It is hypothesized that these characteristics offer novel opportunities for the development of cleansing products that are both highly effective and remarkably gentle. The self-assembly of specific ingredients within alpha-gel systems has the potential to yield stable, mild, and appealing facial cleanser formulations.

Considering the aforementioned circumstances and the limitations of conventional cleansing products, the objective of this research is to develop a facial cleanser that maximizes mildness through the innovative application of alpha-gel technology. The objective is to formulate a product that not only effectively cleanses the skin but also respects its natural balance and barrier function, thereby addressing the growing consumer demand for gentle skincare solutions.

### **2. Materials and Methods**

## 2.1 Materials

The naturally derived polyglyceryl-10 laurate (PG10L), sodium stearoyl glutamate (SG), cetyl alcohol, and stearyl alcohol were procured from cosmetic distributors, while all other raw materials were of cosmetic grade. These ingredients were used to prepare alpha-gel layered cleanser, labeled as Cleaner A.

Two commercial facial cleansers were procured for the purpose of comparative experiments. These products were labeled as Cleanser B and Cleanser C. Cleanser B is a highly regarded mild cleanser, and its main ingredients are water, cetyl alcohol, propylene glycol, sodium lauryl sulfate, stearyl alcohol, methylparaben, propylparaben, and butylparaben. Cleanser C is a popular product that utilizes amino acid surfactants as its primary cleansing agent. Its composition includes the following ingredients: glycerin, potassium cocoyl glycinate, butylene glycol, polyglyceryl-10 myristate, disodium lauryl sulfosuccinate, glyceryl stearate SE, citric acid and other ingredients with concentration lower than 0.1%.

## 2.2 Preparation of layered facial cleanser

Cleanser A was prepared according to the composition listed in Table 1. To prepare the cleanser, Phase A component was subjected to an elevated temperature of 70°C to facilitate dissolution. Subsequently, the Phase B component was subjected to heating at a temperature of 75°C until complete dissolution occurred. Subsequently, Phase B was incorporated into Phase A while maintaining a low stirring speed. Subsequently, Phase AB was cooled to temperatures below 45°C. Subsequently, Phase C was incorporated, and the mixture was agitated at a low speed until homogeneity was achieved. The natural origin index of the formula is calculated in accordance with the international standard ISO 16128.

**Table 1.** Composition of layered facial cleanser.

Phases	Ingredients	w/w (%)
A	Water	73.8
	Chelating agents	0.1
	Preservatives	1.8
	Panthenol	1
	Glycerin	15.5
	Glycereth-26	2.5
	Sodium Stearoyl Glutamate	0.5
	Polyglyceryl-10 Laurate	0.5
B	Cetyl Alcohol	3
	Stearyl Alcohol	1
C	Poloxamer 184	0.3

## 2.3 Characterization with optical microscopy, rheology, differential scanning calorimetry (DSC), and small-wide angle X-ray scattering (SWAXS)

Cleanser A was observed using an optical microscope under normal light source and polarized light source.

To test the rheology properties of cleansers, a rheometer was employed. A precise quantity of the cleansing agent was dispensed onto the parallel plate fixture of the rheometer in a uniform manner. It was ascertained that the specimen was devoid of bubbles and possessed flat edges. The range of shear rates was from 0.1 to 1000 s<sup>-1</sup> and the temperature was kept at 32°C, similar to the surface temperature of the skin.

DSC measurements were performed using a calorimeter. The samples were placed in an aluminum vessel and then the vessel was sealed. The measurement conditions were 2 °C min<sup>-1</sup> for the scan rate and 30-80 °C for the scan range.

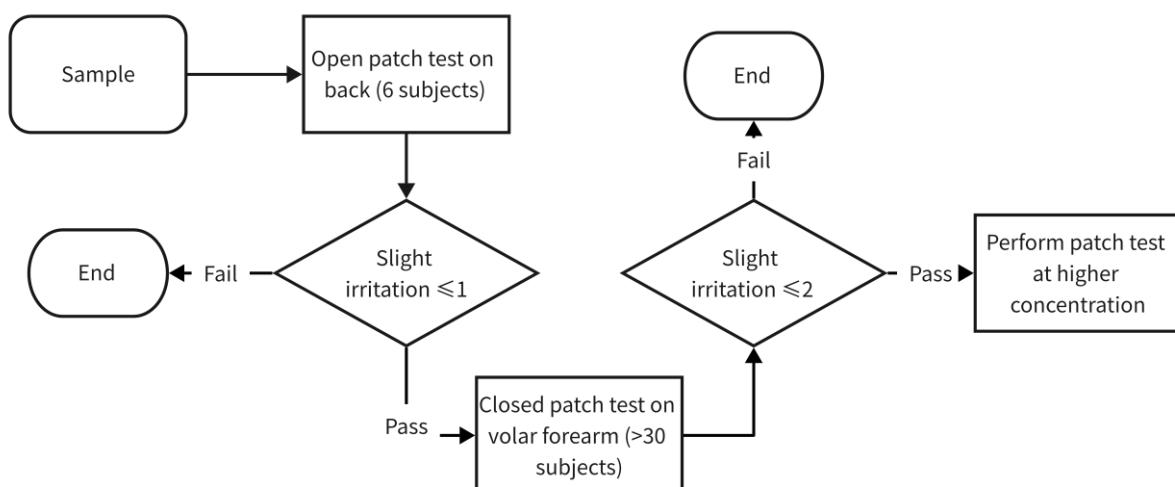
SWAX experiments used X-rays with a wavelength of 0.734 Å. The samples were loaded into the holes of a perforated brass plate, and the plate was sealed with polyimide tape. All experiments were performed at room temperature (25 °C).

## 2.4 Clinical tests

The experimental protocol was conducted in accordance with the Declaration of Helsinki, and all participants provided written informed consent prior to participating in the study.

### 2.4.1 Patch test

The patch test method was principally based on a Chinese regulation *Safety and Technical Standards for Cosmetics 2015 Edition*, yet the passing criteria was stricter. In order to ensure the safety of the subjects during the patch test, the test was divided into two stages, as shown in figure 1. In the initial stage, there were six subjects, and open patches were performed on the subject's back. In instances where the number of slight irritants was one or zero, the second stage of the patch test would be performed on the volar forearm in closed form. The second stage of the test comprised more than 30 subjects. The researcher ascertained that there were at least 30 valid subjects. In instances where the number of individuals exhibiting slight irritation was between 0 and 2, the test was classified as pass. Conversely, when the number of patch tests exceeded or equaled 3, the reaction would be deemed as fail. The test concentration of cleansers was initiated at 1%, and the diluent was purified water. Following the pass of the patch test at this concentration, a 10% concentration test would be conducted. Subsequent to the pass of 10% concentration test, a 100% concentration test would be performed. If the low concentration patch test didn't pass, higher concentration patch test won't be performed, and it would be the end of the test. The results were presented according to the 30-subjects closed patch test data.



**Figure 1.** Flowchart of patch test.

### 2.4.2 Pollution removal test

Two 2\*2 cm<sup>2</sup> square areas were marked on the volar forearms of two subjects, and the oil-dispersed Fe<sub>3</sub>O<sub>4</sub> was applied evenly to the area to simulate dust adhering to the skin. The test area was treated with an appropriate amount of facial cleanser, and the cleanser was massaged evenly across the area. Then, the test area was washed with clean water, and photographs were taken.

### 2.4.3 In vivo efficacy tests including stratum corneum (SC) water content, trans epidermal water loss (TEWL) and a\* value

A total of 31 subjects with sensitive skin were screened for this study. The screening procedure entailed the administration of a lactic acid sting test. The subjects in this study ranged in age from 18 to 60 years old, including 14 females and 17 males. The subjects were instructed to

apply Cleanser A on a daily basis. The evaluation of facial skin SC water content, TEWL and  $a^*$  value was conducted prior to the application of the product, as well as two weeks and four weeks following its use. Prior to each measurement, the subjects were placed in a constant temperature and humidity environment for at least 30 minutes, with a temperature of  $21 \pm 1^\circ\text{C}$  and a humidity of  $50 \pm 10\%$ . Each measurement was performed a minimum of three times, and the results were averaged. The final number of subjects who met the inclusion criteria was 30.

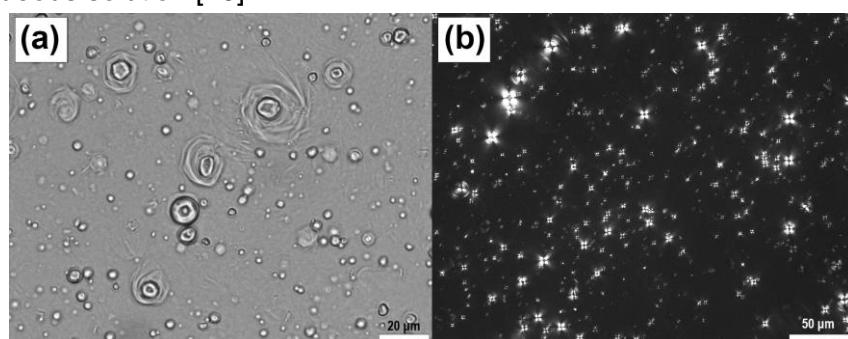
## 2.5 Data analysis

In the course of processing the data, a preliminary investigation in the form of a normal analysis was conducted. The data that conformed to a normal distribution were subjected to a t-test, otherwise the data were subjected to a Wilcoxon signed-rank test. When  $p$  is less than 0.05, the difference of data was considered to be statistically significant.

## 3. Results

### 3.1 Microscopy analysis of Cleanser A

The microstructure of cleanser A was subjected to analysis using an optical microscope, as illustrated in Figure 2. In Figure 2(a), the sample exhibits a distribution of diamond-shaped particles with an approximate particle size range of 1~10  $\mu\text{m}$ . Some particles are enveloped by multi-layered wrappings, giving rise to the formation of "rose-like" shapes. The Maltese cross produced under the polarized light source depicted in Figure 2(b) further indicates the existence of the lamellar structure of Cleanser A [7]. Given the absence of liquid oil in the formula, the system is devoid of round particles. Instead, it contains only irregularly shaped crystal nuclei, which are formed by solid lipids. Surfactants are combined and arranged on the periphery of these crystal nuclei to form a multi-layered structure. In numerous preceding reports, higher fatty alcohols and ionic surfactants are frequently utilized in the formulation of alpha-gel due to their self-assembly properties [8,9]. Generally the critical packing parameter (CPP) of the mixed surfactants in the alpha-gel system is approximately 1, the distance between layers is approximately 6-60nm, and the interlayers can accommodate a substantial amount of aqueous solution [10].

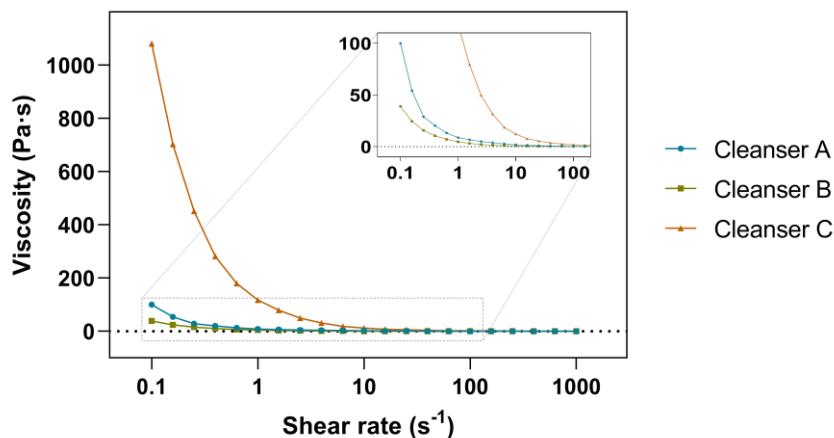


**Figure 2.** Microstructure images of Cleanser A under normal light (a) and polarized light (b).

### 3.2 Rheology study of Cleanser A, Cleanser B and Cleanser C

Figure 3 illustrates the rheological distinctions between Cleanser A and two commercially available cleansers. All three of the aforementioned cleansers exhibit shear-thinning characteristics. It has been demonstrated that Cleanser A and Cleanser B exhibit lower static viscosities. It has been demonstrated that Cleanser C exhibits elevated levels of static viscosity, a property that may be attributed to their augmented surfactant content. This increased surfactant level gives rise to the formation of a substantial number of crystals within the formulation, thereby contributing to the heightened viscosity. The process of crystal accumulation within the formula leads to an increase in its viscosity. However, when subjected

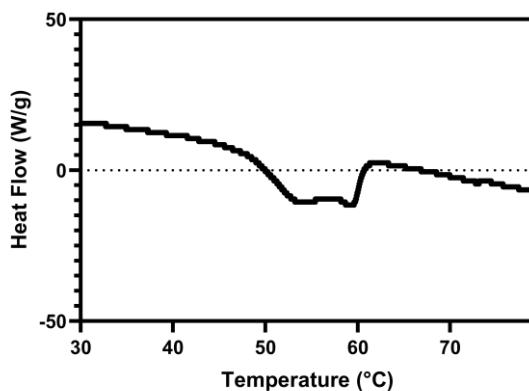
to a shear force, the crystal structure is disrupted, leading to a reduction in viscosity [11]. It has been demonstrated that Cleanser A and Cleanser B contain reduced levels of surfactant, resulting in fewer crystals being formed and, consequently, a lower viscosity. The viscosity of Cleanser A at  $0.1\text{ s}^{-1}$  is  $10\text{ Pa}\cdot\text{s}$ . Generally, a lower viscosity facilitates the rapid mixing of cleansing products with water; however, it is not convenient to use if it is too thin, so the viscosity of cleansing products needs to be controlled within a reasonable range..



**Figure 3.** Viscosity variations of Cleanser A, Cleanser B and Cleanser C with shear rate

### 3.3 DSC and SWAX analysis of Cleanser A

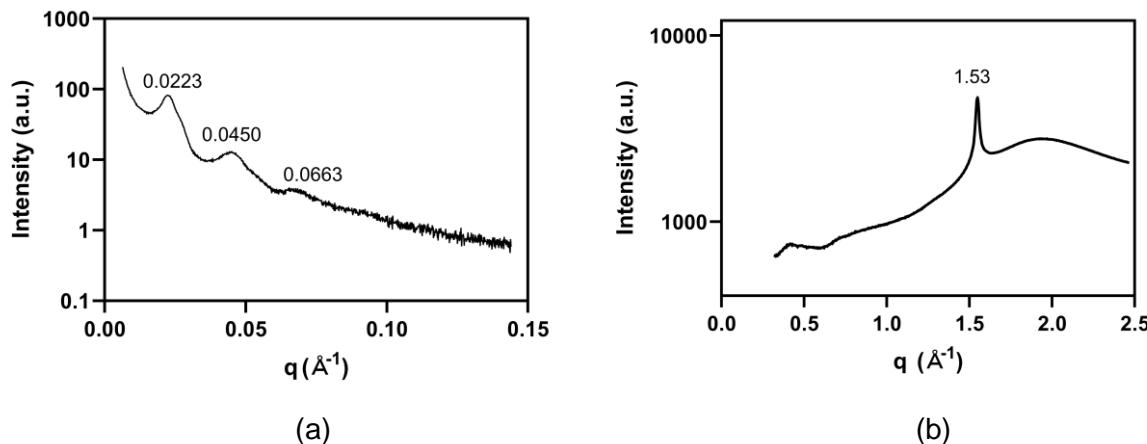
DSC analysis was performed on Cleaner A to investigate the possible crystalline forms. As can be seen from the Figure 4, there are heat change peaks in the range of  $48.5\text{--}61.2\text{ }^\circ\text{C}$ , with two peaks distributed at  $53.7\text{ }^\circ\text{C}$  and  $59.3\text{ }^\circ\text{C}$ . There are a variety of surfactants in the system, and solid lipids include SG, cetyl alcohol and stearyl alcohol. Their melting and crystallization will cause thermal changes. The broader peak range indicates that there are certain combinations of these solid lipids, but they exist in different forms, which may include two- or three-component alpha-gels or single-lipid crystals. If the three solid lipids are combined in a certain ratio, a single absorption peak may be formed [7,12]. However the actual product formulation must take into account stability, safety, cleanability and ease of use, so it's not necessary to pursue a pure alpha-gel system.



**Figure 4.** The DSC image of Cleanser A

The examination of the SAXS image depicted in Figure 5(a) reveals the presence of uniformly spaced peaks with  $q$  value ratio = 1:2:3, suggesting that the system under scrutiny

is composed of layered structures, with a layer spacing of approximately 28 nm. When considered in conjunction with the WAXS image in Figure 5(b), a characteristic peak emerges at  $1.53 \text{ \AA}^{-1}$ , suggesting that the system is an alpha-gel system with a  $d$ -spacing value of 0.41 nm for the inner-layer hexagonal packing [5].



**Figure 5.** The SAXS (a) and WAXS (b) characterization of Cleanser A.

### 3.4 Clinical tests

#### 3.4.1 Patch test

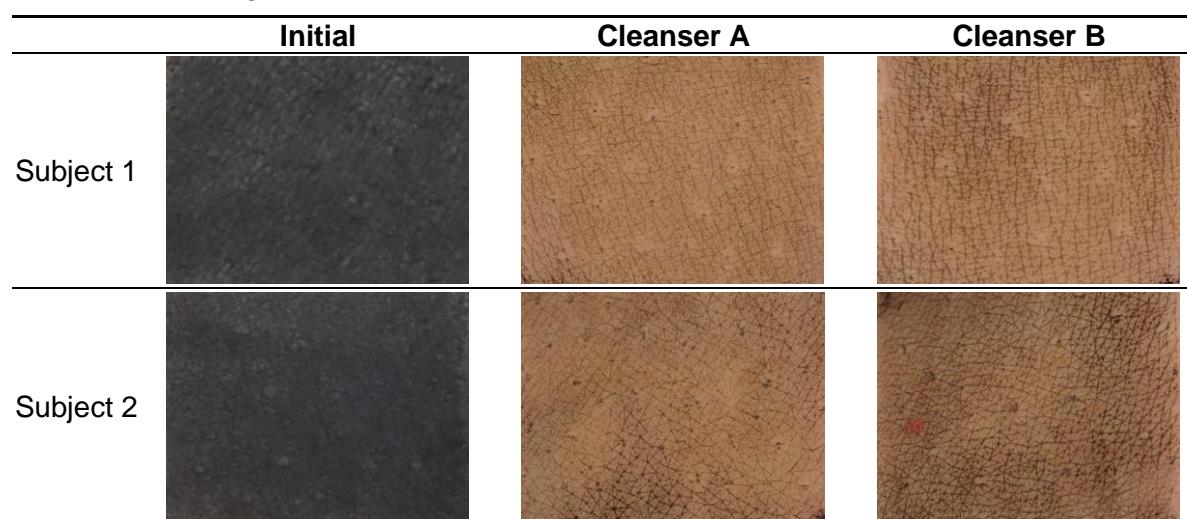
Cleanser A, Cleanser B, and Cleanser C are all relatively mild cleansing products. Cleanser A and Cleanser B exhibit minimal surfactant content, while Cleanser C is predominantly composed of amino acid surfactants. As shown in Table 2, at a concentration of 1%, all three cleansing products passed the patch test. At a concentration of 10%, only Cleanser A and Cleanser B passed the patch test. At a concentration of 100%, only Cleanser A passed the patch test. This finding indicates that Cleanser A exhibits sufficient mildness, even when applied as a leave-on product, achieving a level of mildness that is “100 times” that of conventional products. PG10L possesses a higher molecular weight, and SG features a more substantial alkyl chain, both of which are hallmarks of surfactants that exhibit low irritation potential [13].

**Table 2.** Patch test result of Cleanser A, Cleanser B and Cleanser C at concentrations of 1%, 10% and 100%.

Cleanser	1% water solution	10% water solution	100% sample
A	Pass	Pass	Pass
B	Pass	Pass	Fail
C	Pass	Fail	Fail

#### 3.4.2 Pollutants removal effect of cleansers

As illustrated in the Table 3, a discernible residue of pollutants was present on the skin of both subjects, with subject 2 exhibiting a greater quantity of residue compared to subject 1. For the same subject, Cleanser A has a superior cleaning effect in comparison to Cleanser B. Generally, an increase in cleaning power may necessitate an increase in the amount of surfactant used, which can lead to an escalation in irritation. Cleanser A exhibits a satisfactory level of cleaning efficacy while maintaining a high level of mildness, a property that may be attributed to its balanced composition of surfactants. Poloxamer 184 is incorporated into the formula of Cleanser A. This surfactant is frequently utilized in cosmetic products designed for the removal of maquillage. While it has been demonstrated to enhance cleaning efficacy, it does not itself induce irritation [14].

**Table 3.** Cleansing effect of Cleanser A and Cleanser B

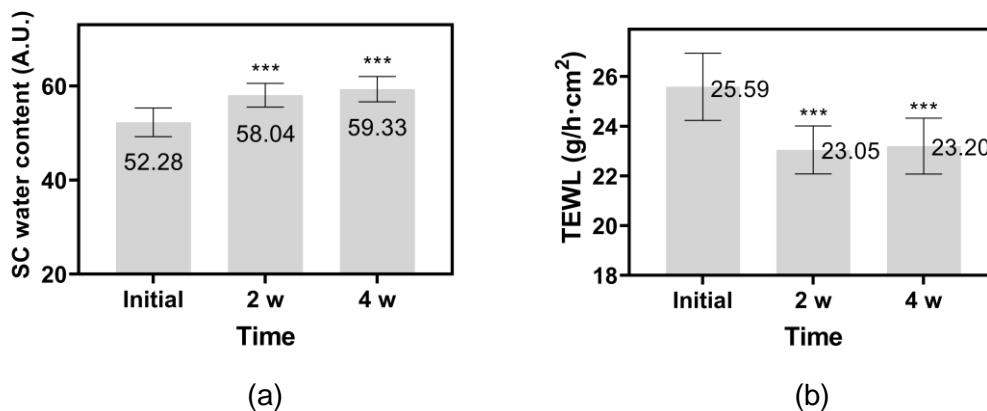
### 3.4.3 Skin barrier protection analysis with stratum corneum water content, TEWL and a\* value after application of Cleanser A

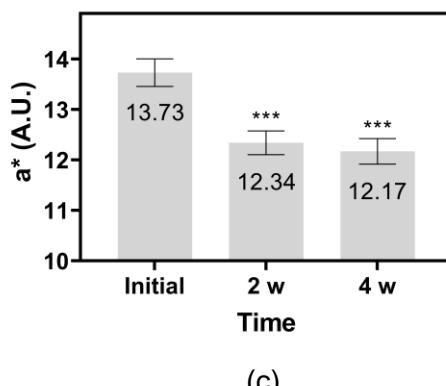
The stratum corneum water content is a significant indicator of skin health [15]. As illustrated in Figure 6(a), following the application of Cleanser A over a period of two weeks, there was an observed increase in the water content of the stratum corneum, from 52.28 A.U. to 58.04 A.U. Subsequent to four weeks of utilization, a further augmentation in moisture content was recorded, reaching 59.33 A.U., thereby suggesting a progressive enhancement in skin hydration over the course of the product's application. This observation indicates a favorable progression in skin condition, indicative of the product's efficacy in promoting hydration and overall skin health.

The TEWL value is a critical indicator of skin barrier function [16,17]. As illustrated in Figure 6(b), following the application of Cleanser A over a period of two weeks, there was a notable decrease in TEWL value, from 25.59 g/h·cm<sup>2</sup> to 23.05 g/h·cm<sup>2</sup>. The findings indicate that the utilization of Cleanser A results in the enhancement of the skin barrier and the reduction of water loss from the skin surface.

The a\* value serves as an indicator for measuring skin sensitivity [18]. The magnitude of the value corresponds to the intensity of the redness of the skin, which may also indicate sensitivity. As shown in Figure 6(c), following the application of Cleanser A, the a\* value exhibited a decline from 13.73 A.U. to 12.17 A.U., suggesting a reduction in skin redness.

The aforementioned data collectively suggest that the application of Cleanser A resulted in enhanced skin barrier function.





(c)

**Figure 6.** The stratum corneum water content(a), TEWL (b) and  $a^*$  value (c) measured before use Cleanser A, after two weeks, and after four weeks. ( $n=30$ , \*\*\*  $p<0.001$ )

#### 4. Discussion

The conventional preparation of facial cleansers involves the incorporation of high concentrations of surfactants and the implementation of high-speed homogenization at elevated temperatures. The process requires substantial thermodynamic and mechanical energy. However, the preparation process of Cleanser A doesn't require high-speed stirring. In addition, a procedure was implemented by transferring a proportion of the water in phase A to the terminal point of the formulation. This procedural adjustment results in a subsequent reduction in heat consumption. This development carries profound implications for the future of energy conservation and the mitigation of carbon emissions. The utilization of reduced surfactant concentrations has the potential to reduce the consumption of oil crops, such as palm and coconut. The natural origin index of Cleanser A, as determined by the ISO 16128 standard, is 94%, which is of reference value for the development of sustainable cleaning products.

The microscope is capable of discerning the morphology of micron-sized particles and utilizes polarized light to ascertain the presence or absence of lamellar structures. Fatty alcohols represent the most prevalent materials utilized in the construction of lamellar structures [19]. However, the capacity of fatty alcohols to establish lamellar structures is inherently limited, necessitating their combination with surfactants that possess elevated HLB values. The "rose"-shaped structure exhibited in this study are formed by the superposition of multiple lamellar structures. These structures envelop the crystal nuclei and are uniformly dispersed throughout the formula. Consequently, this formula can generate viscosity without polymer thickeners, while maintaining stability over an extended period. Alpha-gel systems exhibit thermodynamic instability yet kinetic stability [5]. The lamellar structure formed by solid lipids endows the system with shear-thinning properties, thereby facilitating the mixing and dispersion of cleansing products with water during rubbing and the expulsion of the products from pump bottles [11].

In the course of the patch test, it was demonstrated that Cleanser A exhibits a significantly milder effect than conventional products. This can be attributed to the layered structure of Cleanser A, which enables a gradual release of surfactants [20]. This gradual release ensures that the surfactants do not come into immediate contact with the skin. Concurrently, the minimal surfactant content contributes to its elevated degree of safety. It must be acknowledged that low surfactant content will result in a slight reduction in cleaning effect. Consequently, these products are more appropriate for consumers with medium to dry sensitive skin.

This study has demonstrated that a modification in the cleansing products utilized by consumers with sensitive skin can yield substantial improvements in their skin condition after a

prolonged period of use. This phenomenon can be attributed to the protective barrier provided by the skin, which is maintained under the gentle cleansing force, thereby preventing the loss of essential skin components such as natural moisturizing factors and ceramides. Concurrently, we deliberate on the optimal level of cleansing for the skin. For individuals with sensitive skin, the benefits associated with mildness are of greater importance than the thorough cleansing that is characteristic of other skin care regimens.

Subsequent research endeavors may involve the exploration of methodologies for the optimization of alpha-gel formulations, with the objective of enhancing their mildness and efficacy. This process may entail the empirical evaluation of various surfactant and fatty alcohol combinations. Research on the environmental impact of alpha-gel technology and its potential to reduce manufacturing energy consumption and emissions would also be valuable for promoting sustainability in the cosmetics industry.

## 5. Conclusion

The present study successfully developed an alpha-gel layered facial cleanser (Cleanser A) using poly-glyceryl-10 laurate (PG10L) and sodium stearoyl glutamate (SG). The cleanser exhibited marked mildness, as evidenced by its successful passage through patch tests at all concentrations, and demonstrated effective cleansing capabilities. Microscopic analysis revealed a distinctive “rose-like” microstructure, while rheological measurements indicated favorable shear-thinning properties. Preliminary clinical assessments indicated that the intervention led to significant improvements in skin hydration, enhanced barrier function, and reduced redness. These findings underscore the promise of alpha-gel technology in developing skincare products that are both gentle and effective, catering to the expanding demand for natural and skin-friendly cleansing agents. Subsequent research endeavors may involve the refinement of formulations and the investigation of supplementary benefits associated with alpha-gel systems.

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