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Product Evaluation of a Topical Live Probiotic Serum for Skin Health

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Abstract: Background: *Micrococcus luteus* is a commensal bacterial member on the human skin and is essential in keeping the balance among the various microbial flora of the skin. *M. luteus* strain Q24 or BLIS Q24™ was isolated from the skin of a healthy human adult and has been identified to produce a unique antimicrobial spectrum that is inhibitory towards pathogenic bacteria associated with many skin diseases such as acne. It has been developed as a probiotic with potential applications in improving overall skin health. **Aim:** This study aimed to evaluate the perceived changes in skin quality following topical application of a formulation containing skin commensal probiotic BLIS Q24™. **Materials and methods:** A 28-day study involving 100 adult participants with self-reported normal skin with occasional blemishes or breakouts, topically applied a serum formulation containing BLIS Q24™ to the face. Participants quantitatively evaluated the probiotic serum effect on their skin at baseline Day 0 and then again on Day 10, 20 and 28 of the application. In addition, participants maintained a photo diary to record the perceived changes to their skin. **Results:** A total of 96 participants completed this research. In comparison to the baseline (Day 0), within 10 days, a significant reduction in blackheads (48%), oiliness (48%), blemishes (57%), dry areas (23%), redness/rosacea (45%) and flaky and rough skin (38%) were reported. The probiotic serum was also effective in a significant reduction in fine lines and wrinkles (38%), whiteheads (41%), pimples (55%), age spots (29%), and acne (21%) by the end of 28 days of probiotic application. Overall, there's agreement that probiotic serum delivers or exceeds consumer expectations from the concept and performs just as well, or better, than their regular moisturiser. **Conclusions:** An approach of delivering a live probiotic packaged in an innovative formula to improve several skin conditions in otherwise healthy individuals was found to be successful. This study highlights that a serum formulation containing BLIS Q24™ has a positive impact on skin health with it being effective topically in reducing the appearance of skin blemishes, oiliness, wrinkles, redness, and dryness. BLIS Q24™ offers the potential for the prevention of skin health-related issues and routine maintenance of skin microbiome for healthy skin. **Key Points:** Microbial dysbiosis has been implicated in numerous skin-related issues and a suitable natural alternative is warranted to maintain homeostasis following topical application. A skin commensal probiotic formulation was developed to modulate the skin microbiome to improve a variety of skin quality parameters for a healthier skin profile.

Keywords: live probiotics; topical probiotics; consumer research; skin microbiome; skin health; skin ageing; acne

1. Introduction

The World Health Organization (WHO) 2001 has defined probiotics as "Live micro-organisms which when administered in adequate amounts, confer a health benefit on the host." The significance of balancing good (probiotic) and bad (disease-causing) bacteria has been the focus of skin microbiome research recently. This has also stimulated probiotic development specific to delivering topical solutions for skin health and therefore, more recent research is focussing on developing topical probiotics suitable for maintaining skin health [1], [2], a more logical approach to tackling skin conditions on the target site, i.e. the surface of the skin.

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A key focus currently, with the progression of skin-specific probiotic research, is on balancing the skin microbiome to promote healthier skin. However, there are limited products that contain live bacteria that are more often non-commensal and are derived from sources other than skin typically strains derived from the gut [3], [4]. Typically, these bacteria are not considered to be commensal members of the natural skin microbiota and their role in benefiting skin disorders has not been established. Further, it is inferred that microbes not naturally found on the skin surface are less likely to survive or colonize efficiently on the skin surface in comparison with common skin commensals and the beneficial effects are not well established.

Micrococcus luteus is a commensal bacterial member of the human skin and is essential in keeping the balance among the various microbial flora of the skin [5]. *M. luteus* strain Q24 or BLIS Q24™ was isolated from the skin of a healthy human adult. It has been identified to produce a unique antimicrobial spectrum that is inhibitory towards pathogenic bacteria associated with many skin diseases[6]. It has been shown to be safe [7]. It is being developed as a probiotic with potential applications such as acne control, eczema, psoriasis, impetigo, athlete's foot (tinea), MRSA and body odour and in improving the skin quality parameters [8].

This study was aimed at quantitative evaluation of the effect of a patented [9] topical skin application of a serum containing *M. luteus* Q24 on the skin in terms of perceived change in skin quality parameters and efficacy. The overarching hypothesis was that a formulation containing skin commensal probiotic BLIS Q24™ would improve skin quality upon topical application in vivo in healthy human volunteers.

2. Materials and Methods

2.1. Test product

The probiotic *Micrococcus luteus* Q24 [BLIS Q24™] used in this study is a patented [10] probiotic commensal to humans. The live probiotic hydration serum formulation is also based on a *patent-pending* technology[11]. The probiotic is kept alive in the serum formulation but remains in a state of suspended animation for its entire shelf life (2 yr) under room temperature storage. Once it is applied topically to the skin, the probiotic activates and colonizes and producing metabolites to maintain homeostasis and other skin quality-enhancing effects. The other components of the formulation include Medium-chain triglyceride, silica, and polysorbate 80.

2.2. Cosmetic trial in vivo in healthy human volunteers

The study was conducted across New Zealand by a leading consumer research agency Kantar, New Zealand. A total of 100 participants including 76 females (38 younger females (aged 16 -24y), 38 older females (aged 25-45y), and 24 Males (10 younger males aged (16-24y) and 10 older males (aged 25-45y) were recruited for this study. All participants had self-reported normal skin with occasional blemishes or breakouts with no serious or medical conditions e.g. acne and some level of daily skincare routine that included moisturizing morning or night or both.

In this full-face study, twice daily, participants mix 1 pump of the serum containing the test probiotic serum containing *Medium chain triglyceride* (INCI: Capric Caprylic Triglyceride), *silica* [INCI: Silica Dimethyl Silylate], *polysorbate 80* [INCI: Polysorbate 80], and *BLIS Q24™* [INCI: Micrococcus, Trehalose] with 1 pump of a mild cream [*Purified water* INCI: Aqua], *Glycerol* [INCI: Glycerine], *Xanthan gum* [INCI: Xanthan Gum], *Surfactin* [INCI: Sodium Surfactin], *Vivapur® MCG 811F* [INCI: Microcrystalline Cellulose (MCC) and Sodium Carboxymethyl Cellulose] and applied on the full face for 28 days. Participants were asked to continue to use their regular skincare regime including using other products that they usually use (e.g. cleanser, toner, facemask, scrubs, under-eye cream, serums etc.) but replace their moisturiser/s with the probiotic formulation.

The effect of the topical probiotic BLIS Q24™ was evaluated as the perceived changes in skin quality. The Participants were asked to perform the following:

A) Quantitative Product Evaluation which involved (1) 1x initial survey to measure baseline skin evaluation (D0) and 2) Followed by 3x weekly surveys (D10, D20 and D28) to measure scores for perceived product performance over time. The scores were quantitatively recorded following scoring

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on a 4-point scoring scale as 1) Working well (≥70), 2) Some aspects working well (65-69), Area for improvement (50-64) and Action required (≤49).

B) Online Qualitative Discussion and Photo Diary 1) x 1-day QualBoard (qb4.qualboard.com) events across 28 days, 2) discuss product experience and 3) weekly 'progress report' photo uploads.

Participants were also asked to report any adverse events.

2.3 Statistical analysis

Graph Pad PRISM software was employed for the statistical analysis. The statistical level of significance was set at $p \leq 0.05$ at a 95% confidence interval compared to baseline (D0).

3. Cosmetic results

The benefit of the probiotic serum was demonstrated in the cosmetic trial with significant improvement in several skin quality parameters. A total of 96 participants completed this research. Around 1%, 7%, 13% 21% and 58% of participants reported to have sensitive, oily, dry, normal or a combination of skin features respectively (Figure 1).

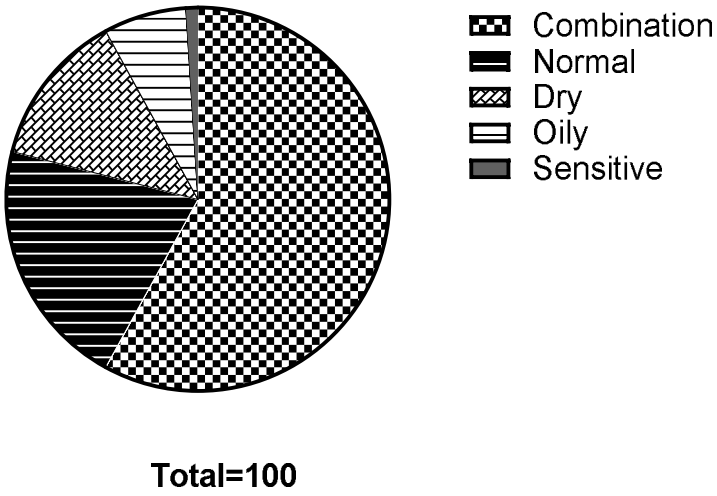

Figure 1. % of participants with self-reported skin types.

Within 10 days, a significant number of participants observed a reduction in blackheads (48%), oiliness (48%), blemishes (57%), dry areas (23%), redness/rosacea (45%) and flaky and rough skin (38%) were reported compared to the baseline (Figure 2 and Figure 3).

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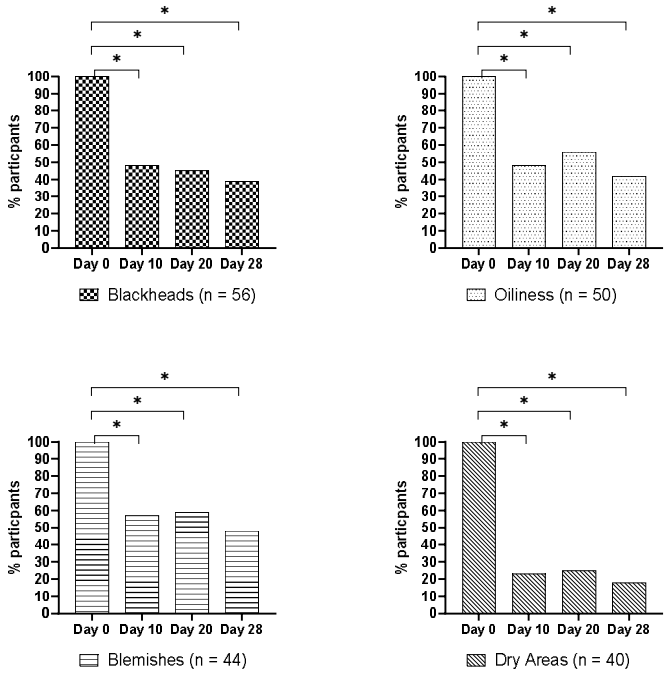

Figure 2. Effect of BLIS Q24™ serum on the skin quality parameters: Blackheads (top left), Oiliness (top right), Blemishes (bottom left) and Dry areas (bottom right). ($p \leq 0.05$ at a 95% confidence interval compared to baseline (D0).

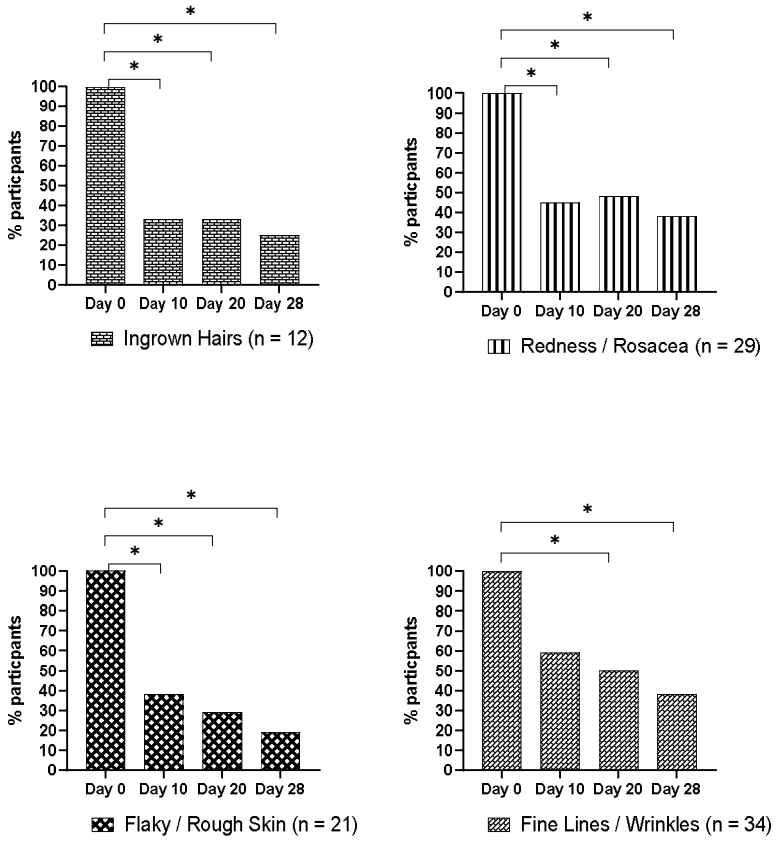

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Figure 3. Effect of BLIS Q24™ serum on the skin quality parameters: Ingrown hairs (top left), Redness/Rosacea (top right), Flaky / Rough Skin (bottom left) and Fine lines and Wrinkles (bottom right). ($p \leq 0.05$ at a 95% confidence interval compared to baseline (D0).

In comparison to D0, the probiotic serum was also effective with a significant number of participants observing a reduction in fine lines and wrinkles (38%), whiteheads (41%), pimples (55%), age spots (29%) and acne (21%) by the end of 28 days of probiotic application (Figure 4).

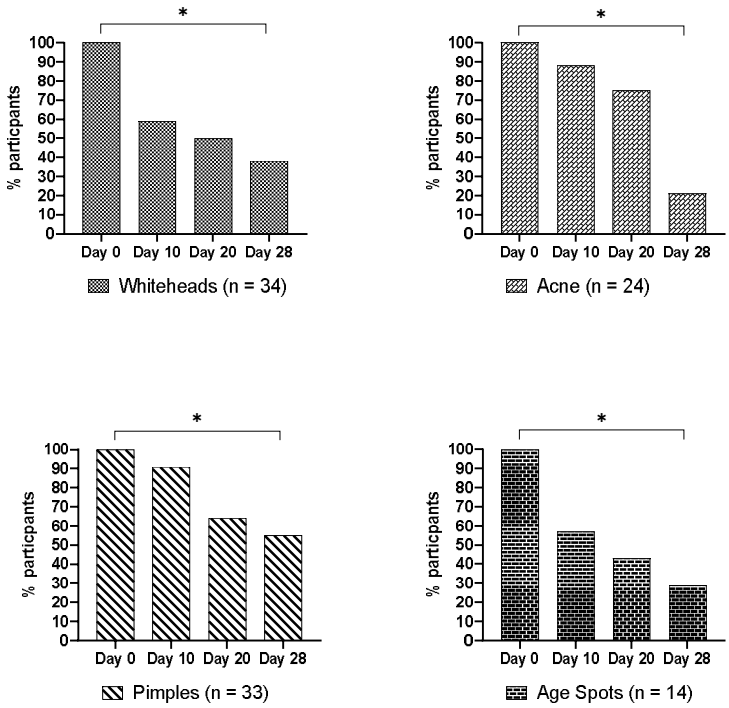

Figure 4. Effect of BLIS Q24™ serum on the skin quality parameters: Ingrown hairs (top left), Acne (top right), Flaky / Rough Skin (bottom left) and Age spots (bottom right). ($p \leq 0.05$ at a 95% confidence interval compared to baseline (D0).

Although not significant, a marked reduction was reported in sunspots, mild dermatitis and milia were also reported (Figure 5).

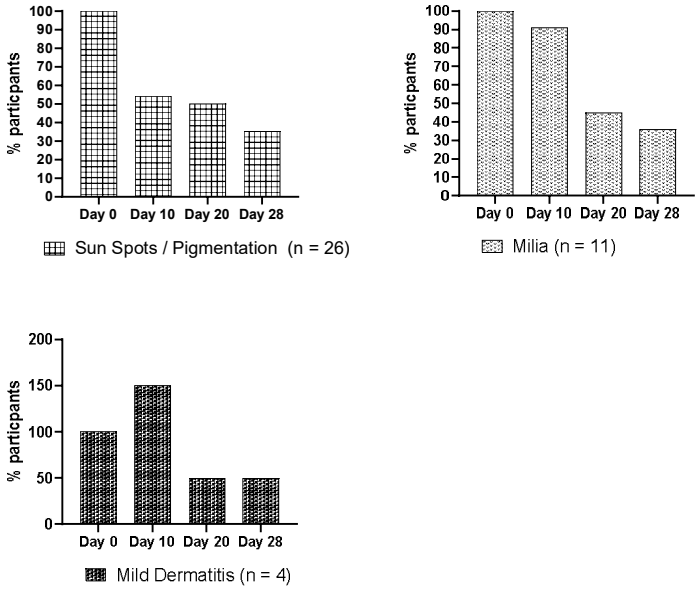

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Figure 5. Effect of BLIS Q24™ serum on the skin quality parameters: Sunspots / Pigmentation (top left), Milia (top right), Mild Dermatitis (bottom left). ($p \leq 0.05$ at a 95% confidence interval compared to baseline (D0).

Participants evaluated the probiotic serum for performance in terms of the overall appeal of the live probiotic serum concept and hydration (Figure 6).

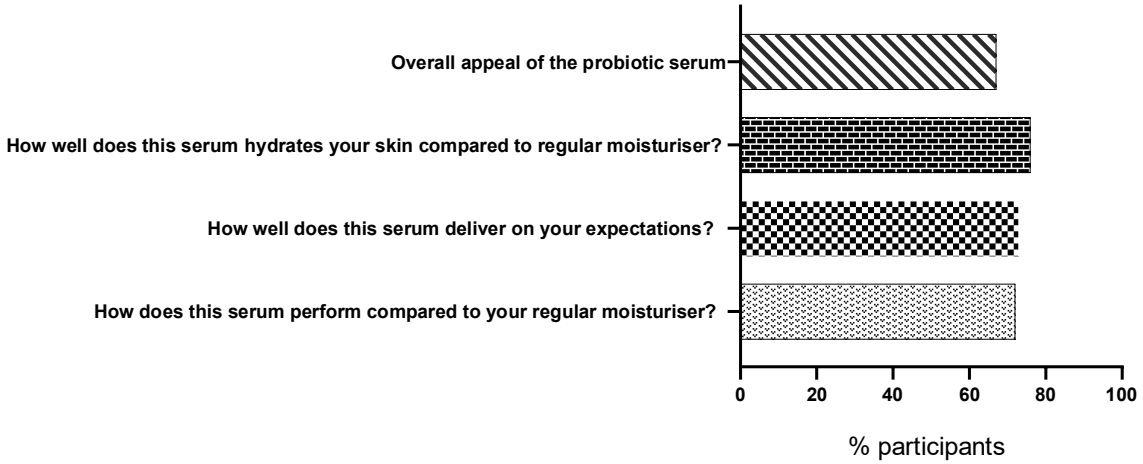
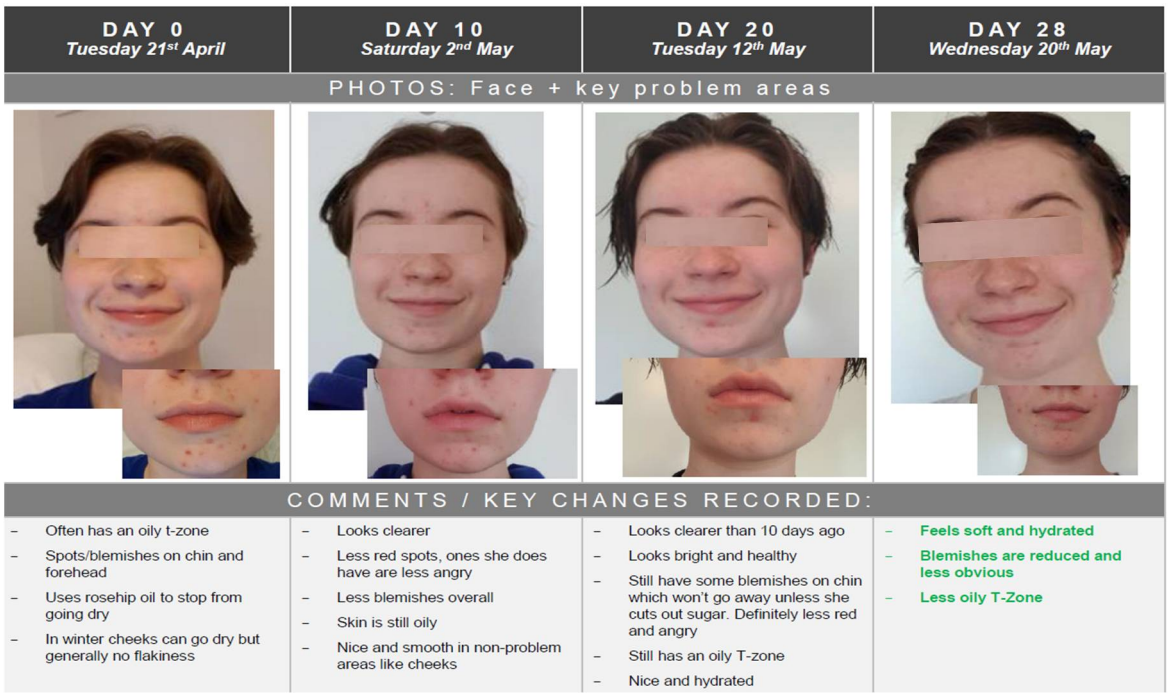


Figure 6. Qualitative evaluation of the performance and hydration ability of the probiotic serum.

There's agreement that probiotic serum delivers or exceeds consumer expectations from the concept and performs just as well, or better, than their regular moisturiser. Overall, by the end of the trial consumers felt positive about the probiotic serum and for some, the experience was life changing.

A snapshot of the skin diary and photo update of one volunteer before the trial and each time point after application of the probiotic serum is shown in Figure 7. A significant improvement from baseline was observed with the clearing of the skin, with skin feeling soft and hydrated and a marked reduction in blemishes by the end of the trial. Taken together, the data highlights the potential of the probiotic serum through an innovative approach that restores homeostasis and improves skin quality. There were no adverse effects reported in the trial.



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4. Discussion

As the largest organ of the body, the skin hosts billions of microbes, in different skin sites [12]. A healthy natural alternative such as probiotics is being sought by a growing number of consumers to help optimize their skin health. Maintaining a healthy skin microbiome has been associated with good skin health via a balanced population of beneficial (good) microbes within the various microbiota associated with the human body.

Oral administration of probiotics targeting gut microbiota [5] has been shown to produce beneficial effects on skin health. However, rather than targeting the gut, it is of merit to deliver skin commensal probiotics directly to the target site i.e. skin, via a topical route to obtain beneficial effects for improving skin health [1]. This route is more suitable as the probiotic will be able to colonize to their natural site and in addition to maintaining homeostasis via their antimicrobial effects, also induce the local skin environment to produce beneficial metabolites that presumably improve skin barrier function and hydration.

The full face 4-week trial showed a significant improvement in several cosmetic parameters as perceived by a large number of participants. The trial, however, suffers the limitation of the absence of a placebo arm nevertheless, these observations encourage the further evaluation of the potential role of *M. luteus* Q24 as a probiotic which not only balances the microbiome but also has a direct effect on the key skin quality indicators as observed from the significant improvement in hydration, reduction of dry patches, age spots, blemishes, sun spots, acne, pimples, oiliness and fine line and wrinkles. Furthermore, similar to previous trials with BLIS Q24™, no adverse effect was observed in this trial, substantiating the safety and tolerability profile of this unique skin probiotic.

5. Conclusions

The imbalance in the microbial diversity and bacterial hyperproliferation has been associated with skin diseases such as acne, impetigo, atopic dermatitis and therefore a balanced skin microbiome has been increasingly seen as a factor impacting the overall skin health. An approach of delivering a live probiotic packaged in an innovative formula to improve several skin conditions in otherwise healthy individuals is presented here.

Micrococcus luteus Q24 (BLIS Q24™) is a human commensal isolated from a healthy adult. It has been shown to colonize well when delivered topically with no adverse side effects. Preliminary investigations have suggested that it has the potential to improve skin conditions such as dry areas and blemishes. In vivo studies have also demonstrated its role in inhibiting the growth of disease-causing pathogens such as *S. aureus*, and *C. acnes*.

This study presents further evidence that a serum formulation containing BLIS Q24™ has a positive impact on skin health with it being effective topically in reducing the appearance of skin blemishes, oiliness, wrinkles, redness and dryness. BLIS Q24™ has therefore proposed for the prevention of skin health-related issues and routine maintenance of skin microbiome for healthy skin.

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