Innovative safe sunscreens technology: skin penetration evaluation through *in vitro* / *in vivo* assays and environmentally friendly

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Abstract

This study presents an innovative non-skin penetrating, and safe sunscreen formulation technology. This new technology utilizes silk peptide polysilicone-14 to microencapsulate UVB absorber octocrylene and UVA absorber butyl methoxydibenzoylmethane (“avobenzone”), all of which are environmentally degradable. The innovative sunscreen was tested and compared with generally formulated sunscreen. Results showed that the innovative sunscreen was non-irritating and non-allergenic in the Human Repeated Insult Patch Test (HRIPT). It exhibited no difference in sun protection efficacy, with SPF around 30 and PFA around 10 *in vivo*. There was no penetration (0.00% penetration rate) of UV absorbers through the membrane in the *in vitro* Franz cell system for up to 6 h post-treatment. Additionally, there was no penetration into the stratum corneum of *in vivo* human skin for up to 4 h post-treatment or into the epidermis for up to 8 h post-treatment, as revealed by Raman spectrometry analysis. The innovative sunscreen was safe for sensitive skin consumers, and sensorial feedback from users was positive. In contrast, the general sunscreen penetrated the skin both *in vitro* and *in vivo* and caused irritation in some sensitive skin consumers. All these data demonstrate that the innovative sunscreen technology can produce non-skin-penetrating and safe sunscreens suitable for fragile and sensitive skin populations.

Key words: sunscreen; microencapsulate; skin penetration; Franz cell; Raman

1. INTRODUCTION

Topical sunscreen application is one of the most effective methods to prevent sun damage to human skin [1]. Although the efficacy and cosmeticity of sunscreens have significantly improved in recent years, one of the major challenges in developing sunscreens is ensuring human safety by preventing skin penetration [2-3]. Clinical findings reveal that sunscreens can permeate the skin and enter systemic circulation [3-5], potentially causing adverse effects, especially estrogenic effects [6-7]. This necessitates the search for effective and safe UV absorbers and formulation technologies that reduce skin penetration activity [1, 4].

Sunscreen mainly targets to protect our skin against UV radiation, which is the root cause for the noxious effects attributed to sunlight. UVC (100 - 280 nm) is absorbed by the atmosphere and does not reach the earth's surface. UVB (280 - 315 nm) reaches the skin's epidermis and damages the surface region, while UVA (315 - 400 nm) penetrates deep into the dermis layer, causing DNA damage, skin burns, wrinkles, and aging [8]. An ideal sunscreen should contain a combination of absorbers effective against both UVB and UVA. Among the available UV absorbers, avobenzone is a widely used and effective UVA absorber [8], but it may be photochemically unstable if not properly formulated [8-10], and its degradation products may cause photo-allergies [11]. Studies have shown that avobenzone has improved stability and comparatively low skin penetration when encapsulated, or when used in conjunction with antioxidants, or formulated as oil-in-water sunscreens [4, 8, 10]. Octocrylene, a commonly used UVB absorber, is also an excellent stabilizer for other UV absorbers, including avobenzone, and enhances the overall formulation [12]. The combination of avobenzone and octocrylene has been reported to provide effective UVA and UVB protection and improved photostability with minimal adverse effects [13]. To reduce skin penetration, various new formulation technologies have been explored [1], with encapsulation [14] and oil-in-water emulsification [4] proving effective in stabilizing UV absorbers and preventing their penetration into the bloodstream [1, 3].

Various methods have been developed to evaluate the skin permeation of sunscreen UV absorbers [3]. *In vitro* methods include flow-through systems, dialyze bags, Franz cell diffusion, and tape stripping, while *in vivo* methods include tape stripping, Raman spectroscopy, and traditional clinical experiments involving blood and urine collection and analysis [3]. Franz cell diffusion is one of the most used *in vitro* methods, has been standardized as OECD TG 428 [15], and uses explants of human skin, pig skin, and engineered membranes. Raman spectroscopy, a non-invasive *in vivo* method that can visualize the penetration profile in the skin, is gaining popularity for cosmetic skin penetration analysis [16-17].

In this study, we present an innovative sunscreen formulation technology using silk peptide polysilicone-14 to microencapsulate octocrylene and avobenzone. The safety, sun protection efficacy, skin penetration activity, suitability for sensitive skin, as well as sensory evaluation of the sunscreen generated by this innovative technology were evaluated through a series of experiments and compared with a general non-encapsulated sunscreen.

2. MATERIALS AND METHODS

2.1 Experiment samples

An innovative sunscreen containing octocrylene and avobenzone (INCI: BUTYL METHOXYDIBENZOYLMETHANE) microencapsulated using silk peptide polysilicone-14 was studied. For comparison, a general sunscreen with minor ingredient modifications, formulated without using the microencapsulation technology, was also studied in parallel. Both samples were formulated as oil-in-water emulsions. The formula information for the two samples is listed in Table I.

Innovative sunscreen		General sunscreen	
Ingredient (INCI name)	Content	INCI 名称	Content
AQUA	83.38%	AQUA	83.13%
GLYCERIN	5.00%	GLYCERIN	5.00%
DIMETHICONE	5.00%	DIMETHICONE	5.00%
OCTOCRYLENE	4.10%	OCTOCRYLENE	4.00%
BUTYLOCTYL SALICYLATE	3.00%	BUTYLOCTYL SALICYLATE	3.00%
CETEARYL ALCOHOL	2.40%	CETEARYL ALCOHOL	2.40%
TITANIUM DIOXIDE	1.92%	TITANIUM DIOXIDE	1.92%
ISONONYL ISONONANOATE	1.48%	ISONONYL ISONONANOATE	1.48%
BUTYL METHOXYDIBENZOYLMETHANE	1.03%	BUTYL METHOXYDIBENZOYLMETHANE	1.00%
PENTYLENE GLYCOL	1.00%	PENTYLENE GLYCOL	1.00%
STEARYL ALCOHOL	1.00%	STEARYL ALCOHOL	1.00%
POTASSIUM CETYL PHOSPHATE	1.00%	POTASSIUM CETYL PHOSPHATE	1.00%
POLYSILICONE-14	0.55%	BUTYROSPERMUM PARKII (SHEA) BUTTER	1.00%
CETEARYL GLUCOSIDE; AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER; PHENOXYETHANOL; ALUMINA; TOCOPHERYL ACETATE; BUTYLENE GLYCOL; PHENOXYETHANOL; HYDROGEN DIMETHICONE; POLYHYDROXYSTEARIC ACID; DISODIUM EDTA; ETHYLHEXYLGLYCERIN	Each < 1.00%	CETEARYL GLUCOSIDE; AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER; PHENOXYETHANOL; ALUMINA; TOCOPHERYL ACETATE; HYDROGEN DIMETHICONE; POLYHYDROXYSTEARIC ACID; DISODIUM EDTA; ETHYLHEXYLGLYCERIN; CITRIC ACID	Each < 1.00%

Table I - The innovative sunscreen and general sunscreen formula information.

2.2 Human Repeated Insult Patch Test (HRIPT)

The test was conducted following the HRIPT method as outlined in Chapter 2 of the China Safety Technical Specifications for Cosmetics (2015 Edition) [18]. Briefly, 30 volunteers (6 male and 24 female), aged 20 to 46 years (average age 26.6 ± 6.0 years), who met all the inclusion criteria, participated in the study. A sample of 0.020 - 0.025 g was applied to a 50-mm² area on the forearm (one sample per forearm) for 24 h. After 24 h, the samples were removed, and the skin response was evaluated at 0.5, 24, and 48 h post-treatment. The skin response was recorded according to the specified method.

2.3 In vivo SPF and PFA value Test

The test was performed following the sun protection test SPF and PFA determination methods as described in Chapter 8 of the China Safety Technical Specifications for Cosmetics (2015 Edition) [18].

2.3.1 SPF Determination

For SPF determination, 10 volunteers (7 males and 3 females), aged 21 to 55 years (average age 36.4 ± 11.9 years), who met the inclusion criteria, participated in the test. Before testing, the minimum erythema dose (MED) value of the subjects' skin to 290 – 400 nm UV radiation was determined by exposing five points on their backs to varying dosages of UV radiation. The lowest dosage that caused red spots 24 h post-radiation was considered the MED. On the day of testing, a sample of (2.00 ± 0.05) mg/cm² was applied to five spots on the back. The irradiation dosages were selected according to the standard requirements and were carried out under four conditions: 1) Normal skin. 2) Skin coated with a reference substance (prepared according to the high SPF standard). 3)Skin coated with the innovative sunscreen. 4)Skin coated with the general sunscreen. After 24 h, the MED for the four conditions were recorded, and SPF was calculated as the MED value of protected skin divided by the MED value of unprotected skin.

2.3.2 PFA Determination

For PFA determination, 10 volunteers (6 males and 4 females), aged 30 to 52 years (average age 38.6 ± 6.5 years), who met the inclusion criteria, participated in the test. The test procedures were similar to SPF testing. Before the test, the minimum persistent pigment darkening (MPPD) value of the subjects' skin to 320 – 400 nm UV radiation was determined and recorded at the end of the test. PFA was calculated as the MPPD value of protected skin divided by the MPPD value of unprotected skin.

2.4 Skin penetration analysis

2.4.1 In vitro Franz cell system assay

The percutaneous permeation of both octocrylene and avobenzone from the two sunscreen samples was evaluated following OECD TG 428 for *in vitro* dermal absorption testing [15] and a reported study [4]. Briefly, a Strat-M membrane (Merck Millipore, Japan) was placed in a vertical Franz cell system (PermeGear, Inc., Hellertown, PA, USA) with the stratum corneum facing up. The receptor solution consisted of 20 mM phosphate-buffered saline (PBS; pH 5.8) and ethanol in a 1:1 ratio (v/v). After equilibrating the membrane by ensuring tight contact with the receptor solution for 30 minutes, the sunscreen sample was applied to the membrane surface. The permeation of the UV absorbers was determined at 2, 4, 6, 8, and 24 h post-application using high-performance liquid chromatography (HPLC) analysis, as described in Chapter 5 of the China Safety Technical Specifications for Cosmetics (2015 Edition) [15].

2.5 In vivo Raman spectroscopy evaluation

The Raman test was conducted in accordance with GB/T 40219-2021 General Specification for Raman Spectrometer [19]. A volunteer with forearm test area cleaned was acclimated to (22 ± 2) ℃ and (50 ± 10) % humidity for 30 min. Each sample was applied at 5 mg/cm^2 to a 1 × 1 cm^2 skin area for 30 min and then washed off. At 1, 2, 4, 6, 8, 10 and 12 h post-application, spectra from 2 points within the test area were collected in parallel, each point being measured five times using a point-by-point mapping approach in an x-z-coordinate system with 5 μm depth difference and a 20 × 120 μm scanning area. Measurements were taken using the LabRAM Odyssey (HORIBA) at 2.68 mW laser power and

0.5 s integration time. Raman spectrometry data was analyzed using Labspec (HORIBA) software. Statistics were performed using ORIGIN 2017.

2.6 In vivo clinical tests

2.6.1 Sensitive skin evaluation

The test was performed according to T/GDCA 029—2023 Evaluation of Cosmetics for Sensitive Skin [20]. Briefly, 30 volunteers with sensitive skin, as classified by the standard's subjective evaluation form and who met the inclusion criteria, participated in the test. Subjects applied the innovative sunscreen (labeled as sample 1) to the left side of their face and the general sunscreen (labeled as sample 2) to the right side once per day for four consecutive weeks. The subjects were interviewed on days 7, 14, 21, and 28 to record any adverse reactions, including itching, redness, burning, or stinging.

2.6.2 Sensory evaluation

The test was performed following T/GDCA 003—2020 General Rules for Sensory Evaluation of Cosmetics [21]. Briefly, 20 volunteers who met the standard requirements acclimated to an environment of (22 ± 2) °C and (50 ± 5) % humidity for at least 10 minutes. They then applied 0.2 mL of the innovative sunscreen (labeled as sample 1) and the general sunscreen (labeled as sample 2) to each half of their face by rolling 10 times. The spreadability and scrubbiness during application, as well as stickiness, refreshing feeling, residue, nourishment, softness, shininess, and skin naturalness at 2 minutes post-application, were evaluated. Each attribute was rated on a scale of 1 to 5, where 1 indicated "very disagree," 2 "disagree," 3 "neutral," 4 "agree," and 5 "very agree."

2.6.3 Statistical analysis

The results were expressed as Mean ± SEM. Comparisons between groups were performed using two-tailed t-test and Wilcoxon signed-rank test, and $p < 0.05$ was considered as a significant difference.

3. RESULTS

3.1 HRIPT test

All volunteers showed no adverse reactions to either of the two samples, indicating that the sunscreens were mild and non-irritating to general human skin.

3.2 In vivo clinical SPF and PFA value test

The *in vivo* clinical SPF and PFA value test results were summarized in Table 2. The results showed the SPF was around 30, PFA was around 10, and SPF/PFA ratio < 3 for both the innovative and general sunscreen. There was no obvious difference in terms of SPF and PFA between the innovative and general sunscreen, which means the innovative sunscreen formulation technology did not affect the sun protection efficacy of the formula.

Sample	SPF (Mean ± SEM)	PFA (Mean ± SEM)	SPF/PFA ratio
Innovative sunscreen	30.2 ± 0.3	10.4 ± 0.2	< 3
General sunscreen	31.0 ± 0.2	11.6 ± 0.2	< 3

Table II - The *in vivo* clinical test measured SPF and PFA values.

3.3 Skin penetration analysis

3.3.1 In vitro Franz cell system assay

The Strat-M-Franz cell system was used to investigate the skin penetration activity of octocrylene and avobenzone from the innovative and conventional sunscreen samples, respectively. A PBS treatment group was included as a blank control. Each group was tested in triplicate. The concentration of UV absorbers in the PBS receiving solution at 2, 4, 6, 8, and 24 h post-treatment was measured using HPLC analysis. The results (Tables III and IV, Fig. 1) revealed that for the innovative sunscreen, neither octocrylene (Table III) nor avobenzone (Table IV) was detected up to 6 hours. At 8 hours, 8.1 μg/cm² (0.04%) octocrylene and 8 μg/cm² (0.17%) avobenzone were detected, while at 24 hours, 264 μg/cm² (1.44%) octocrylene and 41 μg/cm² (0.90%) avobenzone were detected. For the general sunscreen, 38.9 μg/cm² (0.14%) octocrylene and 18.8 μg/cm² (0.25%) avobenzone were detected at 2 hours, with their concentrations gradually increasing to 1749 μg/cm² (6.08%) and 316 μg/cm² (4.20%) respectively at 24 hours. These results demonstrate that the innovative microencapsulation technology significantly reduces the skin penetration of UV absorbers in sunscreen.

Weight (μg/cm²) (%)	2 h	4 h	6 h	8 h	24 h
Innovative sunscreen	0 (0.00%)	0 (0.00%)	0 (0.00%)	8.1 (0.04%)	262 (1.44%)
General sunscreen	38.9 (0.14%)	71.8 (0.25%)	97.5 (0.34%)	154.6 (0.54%)	1749 (6.08%)

Table III - The cumulative amount of octocrylene permeated through the Strat-M membrane.

Weight (μg/cm²) (%)	2 h	4 h	6 h	8 h	24 h
Innovative sunscreen	0 (0.00%)	0 (0.00%)	0 (0.00%)	8 (0.17%)	41 (0.90%)
General sunscreen	18.8 (0.25%)	21.4 (0.29%)	28 (0.37%)	29.8 (0.40%)	316 (4.20%)

Table IV - The cumulative amount of avobenzone permeated through the Strat-M membrane.

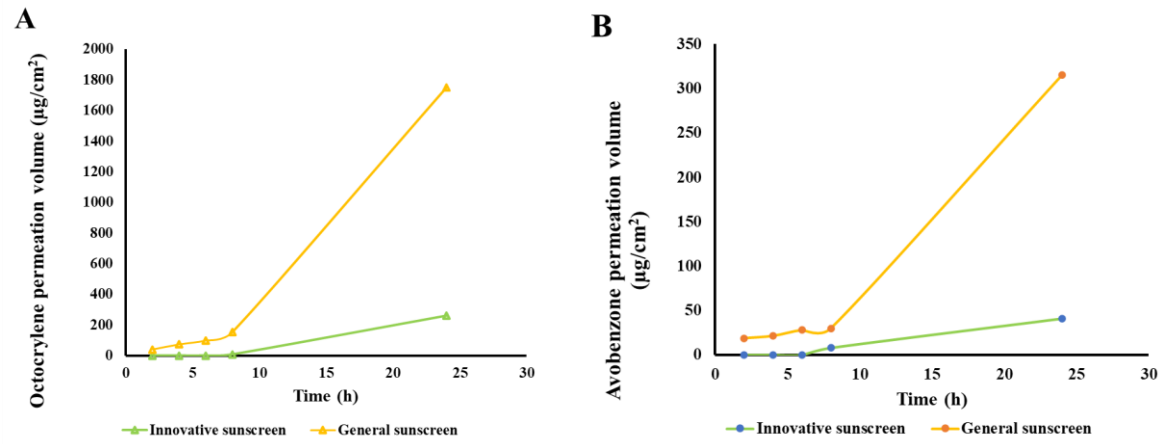


Figure 1 - The cumulative amount of octocrylene (A) and avobenzone (B) permeated through the Strat-M membrane.

3.4 In vivo Raman spectroscopy evaluation

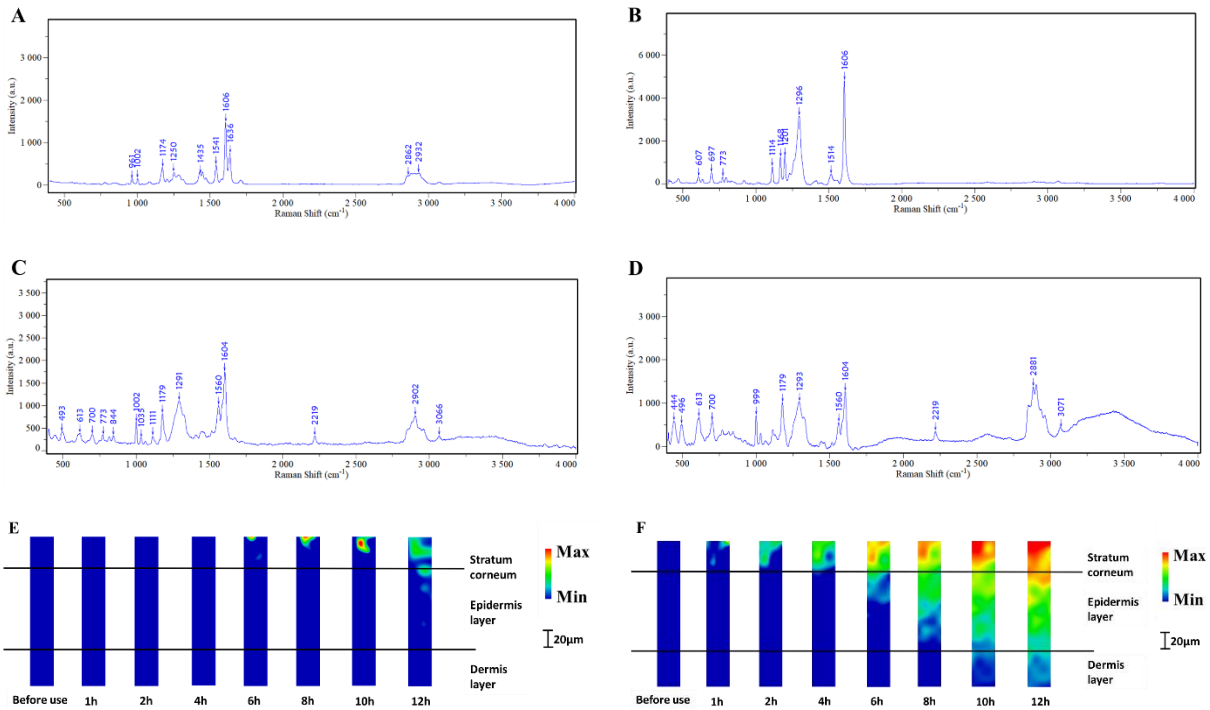
This permeability test uses the characteristic Raman signal that distinguished the sample from the skin intrinsic signal to confirm its distribution in different skin depth spaces. Before the sample skin penetration analysis, the intrinsic Raman spectra of human skin *in vivo* and their corresponding representative components were analysed and summarized in Table V.

Peak position (cm^{-1})	Vibration mode	Principal representative component
943	N(C-C) skeleton, collagen skeleton	Proline, hydroxyproline
1275	C-N absorption band (amide III band)	Glycine skeleton, proline, nucleic acid
1455	C-H bending pattern of protein (CH_2 stretching/CH_3 asymmetric change shape)	Structural protein, elastin
1655	vC=O stretching vibration (amide I band, containing α-fold, β-fold and random crimp)	Actin, collagen, keratin
2846	Asymmetric stretching of CH_2	Lipid
2882	Symmetric stretching of CH_2	Lipid
2934	Asymmetric stretching of CH_3	Lipids and proteins

Table V - The attribution of Raman characteristic peaks and their representative components.

The Raman spectra characteristic peaks for octocrylene (Fig. 2A) were 961 cm^{-1}, 1002 cm^{-1}, 1174 cm^{-1}, 1250 cm^{-1}, 1435 cm^{-1}, 1541 cm^{-1}, 1606 cm^{-1}, I636 cm^{-1}, 2862 cm^{-1} and 2932 cm^{-1}, and for avobenzone (Fig 2B) were 444 cm^{-1}, 496 cm^{-1}, 613 cm^{-1}, 700 cm^{-1}, 999 cm^{-1}, 1179 cm^{-1}, 1293 cm^{-1}, 1560 cm^{-1}, 1604 cm^{-1}, 2219 cm^{-1}, 2881 cm^{-1} and 3071 cm^{-1}. The full spectra of octocrylene and avobenzone were used to track their *in vivo* skin penetration in the two sunscreens samples. The Raman spectra characteristic peaks for the innovative sunscreen (Fig. 2C) were 493 cm^{-1}, 613 cm^{-1}, 700 cm^{-1}, 773 cm^{-1}, 844 cm^{-1}, 1002 cm^{-1}, 1035 cm^{-1}, 1111 cm^{-1}, 1179 cm^{-1}, 1291 cm^{-1}, 1560 cm^{-1}, 1604 cm^{-1}, 2219 cm^{-1}, 2902 cm^{-1} and 3066 cm^{-1}, and for the general sunscreen (Fig. 2D) were 444 cm^{-1}, 496 cm^{-1}, 613 cm^{-1}, 700 cm^{-1}, 999 cm^{-1}, 1179 cm^{-1}, 1293 cm^{-1}, 1560 cm^{-1}, 1604 cm^{-1}, 2219 cm^{-1}, 2881 cm^{-1} and 3071 cm^{-1}.

In-depth analysis of the Raman images revealed the content distribution map at different depths of the skin for octocrylene and avobenzone. For the innovative sunscreen, octocrylene (Fig. 2E) did not penetrate into the stratum corneum within 4 h. At 6, 8 and 10 h, a small amount of it penetrated into the stratum corneum. At 12 h, it broke through the cuticle and entered the active epidermis. The relative permeation rate of octocrylene at 1, 2, 4, 6, 8, 10 and 12 h were 0%, 0%, 0%, 0.21%, 0.70%, 1.74% and 2.12% respectively. Similar to octocrylene, avobenzone (Fig. 2F) also did not penetrate into the stratum corneum within 4 h. At 6, 8 and 10 h, a small amount of it penetrated into the stratum corneum. At 12 h, it broke through the cuticle and entered the active epidermis. The relative permeation rate of avobenzone at 1, 2, 4, 6, 8, 10 and 12 h were 0%, 0%, 0%, 0.31%, 1.79%, 2.55% and 3.13% respectively. For the general sunscreen, the octocrylene (Fig. 2G) penetrated into the stratum corneum within 1 h, continued to permeate continuously in the stratum corneum within 2 and 4 h, broke through the cuticle and entered the active epidermis within 6 h, permeated continuously in the stratum corneum and active epidermis within 8 h, broke through the active epidermis and entered the dermis at 10 h. The relative permeation rate of octocrylene at 1, 2, 4, 6, 8, 10 and 12 h were 0.89%, 2.03%, 3.19%, 5.33%, 7.25%, 10.03% and 12.58% respectively. Similarly, the avobenzone (Fig. 2H) penetrated into the stratum corneum, and a small amount penetrated into the active epidermis at 1, 2 and 4 h, continued to penetrate the stratum corneum and the active epidermis at 6, 8 and 10 h, and broke through the active epidermis into the dermis, and continued to permeate the stratum corneum, the active epidermis and the dermis at 12 h. The relative permeation rate of the avobenzone at 1, 2, 4, 6, 8, 10 and 12 h were 1.12%, 2.75%, 3.32%, 5.66%, 7.43%, 7.92% and 9.17% respectively. Calculation of the accumulated penetration volume of octocrylene (Fig. 2I) and avobenzone (Fig. 2J) at varying time points clearly exhibited that compared with the general sunscreen, the innovative sunscreen technology completely blocked UV absorbers penetrate into the stratum corneum for up to 4 h, and blocked the penetration into the active epidermis for 8 to 10 h. All these data further demonstrated that the innovative microencapsulation technology effectively decreased the penetration of UV absorbers into human skin.



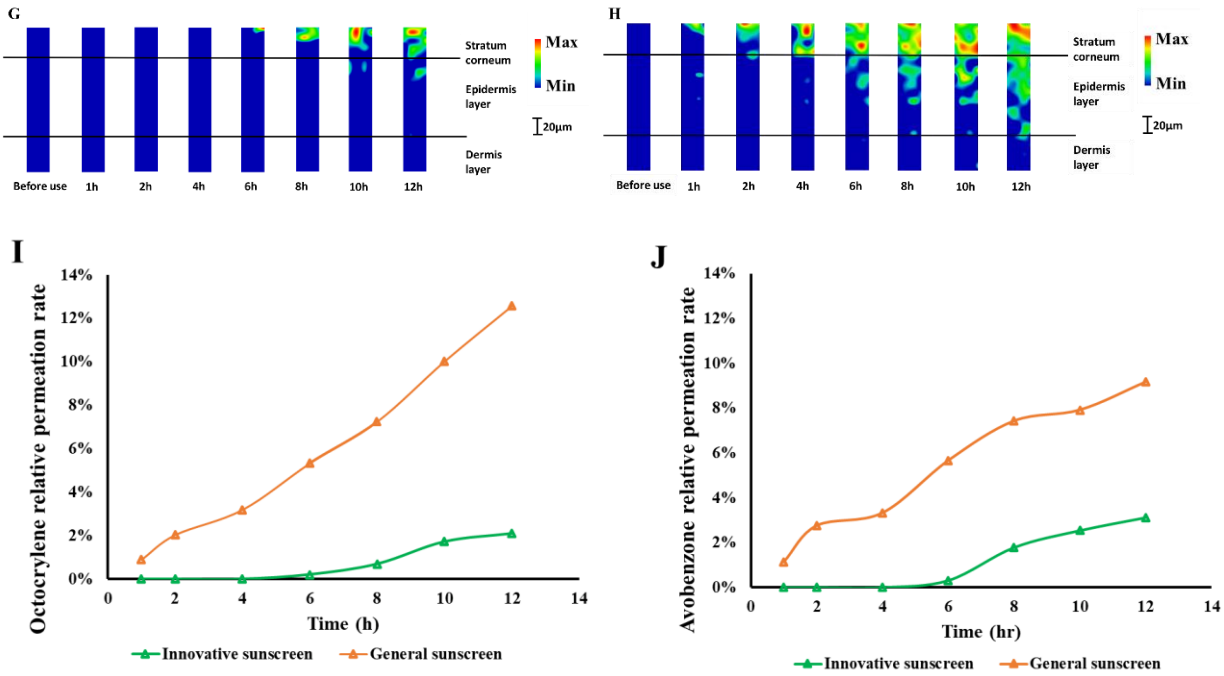


Figure 2 - The Raman spectrometry analysis found very low skin permeation of UV absorbers octocrylene and avobenzone from the innovative sunscreen compared to the general sunscreen. Raman spectrogram of octocrylene (A), avobenzone (B), innovative sunscreen (C) and general sunscreen (D). Content distribution map at different depths of the skin for octocrylene in the innovative (E) and general sunscreen (F), and for avobenzone in the innovative (G) and general sunscreen (H). Permeation volume of octocrylene (I) and avobenzone (J) in the skin for both the innovative and general sunscreens.

3.5 In vivo clinical tests

3.5.1 Sensitive skin evaluation

Thirty sensitive skin volunteers joined and finished the 4-week clinical trial. The results were summarized in Table VI. For the innovative sunscreen (sample 1), only 1 subject (3.33%) reported itch and the rest 29 subjects (96.67%) reported no adverse response at D7, and all subjects reported no adverse response at D14, D21 and D28. According to the T/GDCA 029 - 2023 standard, if ≥ 96.67% sensitive skin subjects reported no adverse response to a sample, the sample can be regarded as mild, non-irritating and suitable for sensitive skin consumers. Thus, the innovative sunscreen was classified as suitable for sensitive skin consumers. For the general sunscreen (sample 2), 3 subjects (10%) reported adverse responses including itch, redness and burning at D7, 2 subjects (6.67%) reported itch and redness respectively at D14 and D21, and 1 subject (3.33%) reported redness at D28. As the subject no adverse response rate < 96.67%, the general sunscreen was regarded as irritating and not suitable for sensitive skin consumers. These results indicated that the microencapsulation technology used to formulate the innovative sunscreen reduced the irritation of the product to sensitive skin consumers.

Sample	Skin response	Days				Percentage			
		D7	D14	D21	D28	D7	D14	D21	D28
Innovative sunscreen	No response	29	30	30	30	96.67%	100.00%	100.00%	100.00%
	Itch	1	0	0	0	3.33%	0.00%	0.00%	0.00%
	Redness	1	0	0	0	3.33%	0.00%	0.00%	0.00%
	Burning	0	0	0	0	0.00%	0.00%	0.00%	0.00%
	Others	0	0	0	0	0.00%	0.00%	0.00%	0.00%
General sunscreen	No response	27	28	28	29	90.00%	93.33%	93.33%	96.67%
	Itch	2	1	1	0	6.67%	3.33%	3.33%	0.00%
	Redness	1	1	1	1	3.33%	3.33%	3.33%	3.33%
	Burning	1	0	0	0	3.33%	0.00%	0.00%	0.00%
	Others	0	0	0	0	0.00%	0.00%	0.00%	0.00%

Table VI - Sensitive skin volunteers' subjective evaluation results.

3.6 Sensory evaluation

All twenty volunteers reported no adverse responses to both the innovative and general sunscreen during the experiment. Based on their sensory grading for both samples in terms of spread ability and scrubbiness during the application process, as well as stickiness, refreshing feeling, residue, nourishment, softness, shininess, and skin naturalness at 2 minutes after application, statistical analysis found that the volunteers' grading for all ten endpoints fitted a normal distribution ($p < 0.05$) for both samples. Comparative analysis of the grades between the two samples showed no significant sensory difference ($p > 0.05$) between the innovative and general sunscreen. The grades for both samples are presented in the sensory profile map in Fig. 3. Overall, the volunteers agreed that both sunscreen samples provided good sensory experiences.

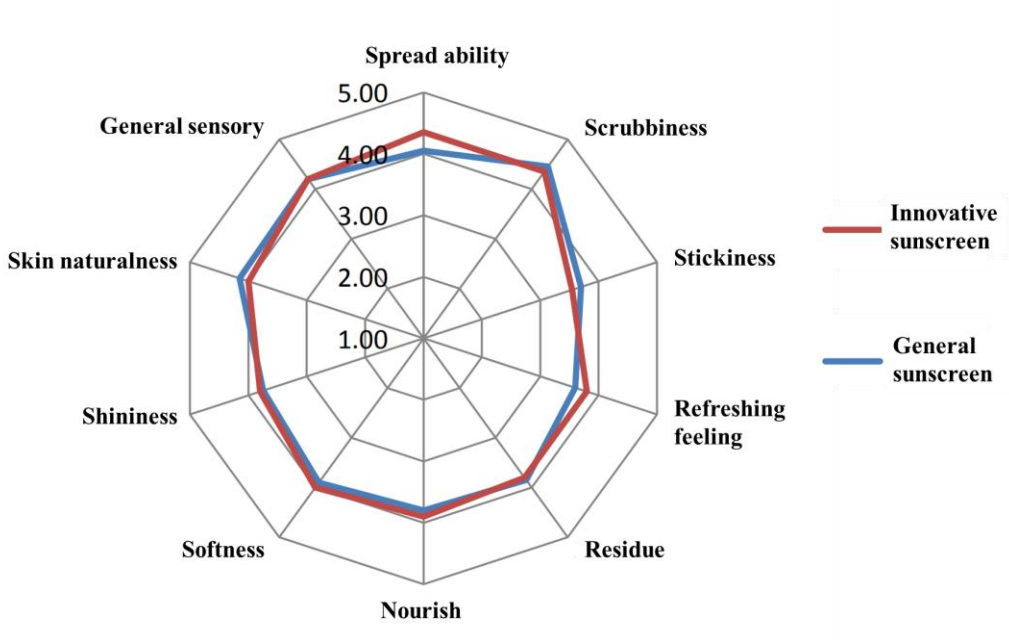


Figure 3 - Sensory evaluation map of the innovative and general sunscreen.

4. DISCUSSION

Sunscreens are expected to remain on the skin's surface to enable UV absorbers to protect effectively against UV damage. However, the penetration of UV absorbers into the skin is often inevitable [3-5, 23], and undesirable due to potential health risks such as endocrine disruption and irritation after entering systemic circulation [24-25]. Additionally, factors like an uncomfortable oily and airtight sensation, unnatural appearance, and environmental concerns can affect consumers' willingness to use sunscreen [8].

This study describes an innovative sunscreen technology designed to produce sunscreens that are safe, effective, exhibit low skin penetration, have good sensory properties, a natural appearance, and are environmentally friendly. An innovative sunscreen was formulated using this technology, incorporating the UVB absorber octocrylene and the UVA absorber avobenzone, selected based on internal research findings and published studies [3, 4, 22]. Polysilicone-14, a silk polypeptide, was chosen as the microencapsulation material. Octocrylene and avobenzone were first encapsulated by polysilicone-14 and then incorporated into an oil-in-water sunscreen formulation.

The attributes of the innovative sunscreen were evaluated through six *in vitro* and *in vivo* experiments, with a similar general sunscreen used as a control. The results showed that the innovative sunscreen was safe in the Human Repeated Insult Patch Test (HRIPT), had comparable sun protection efficacy (SPF around 30 and PFA around 10) *in vivo*, and was well-received by volunteers for its sensory properties and natural appearance. Importantly, the innovative sunscreen outperformed the general sunscreen in terms of skin penetration and suitability for sensitive skin.

Raman spectrometry analysis demonstrated that the UV absorbers in the innovative sunscreen did not penetrate the stratum corneum within 4 hours post-treatment, and only a small amount penetrated the stratum corneum without breaching the cuticle to enter the active epidermis up to 10 hours post-treatment. This indicates that the innovative formulation effectively addresses the concern of UV absorber skin penetration. Additionally, research has found that sunscreens with an SPF-to-PFA protection factor ratio of less than 3 provide the most effective protection [22]. The innovative sunscreen had a measured SPF-to-PFA ratio of 30.2 to 10.4, meeting this requirement perfectly [8, 14, 26]. Furthermore, the selected UV absorbers octocrylene and avobenzone, along with polysilicone-14, are all environmentally degradable, which was a key consideration in developing the innovative formulation technology.

The innovative polysilicone-14 microencapsulation technology presented in this study represents a breakthrough in addressing the skin penetration challenge of sunscreen UV absorbers. The resulting sunscreen provides a safe and effective option for consumers, including those with fragile and sensitive skin.

5. CONCLUSION

In this study, we conducted a series of experiments to evaluate the safety and skin penetration activity of an innovative sunscreen formulated using polysilicone-14 microencapsulation technology. The microencapsulation technology effectively prevented the skin penetration of UV absorbers into the epidermis for up to 10 hours, without compromising the sun protection efficacy or sensory qualities of the final product. This innovative formulation technology offers a solution for developing safe and effective sunscreen products that are also suitable for consumers with fragile and sensitive skin. Additionally, this microencapsulation technology can be adapted to develop sunscreens that meet various consumer needs.

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7. CONFLICT OF INTEREST STATEMENT

None

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