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Safety and Efficacy of Palm-based Ingredients in Cosmetic and Personal Care Products

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ABSTRACT

Safety and efficacy evaluation of the active ingredients or the cosmetic products themselves is important to ensure customer safety, and to substantiate claims. As newly synthesized or extracted ingredients become available in the cosmetics and personal care industry, new cosmetics are continually being formulated to capture new market segments. The rapid development of new actives and formulated products has increased the demand for safety and efficacy evaluation so as to ensure the safe use and effectiveness of the products. Furthermore, safety and efficacy data are required by the regulating authority in order to ensure that the industry conforms to the cosmetic legislation. Palm-based cosmetics are formulated with oleochemicals and palm-based actives such as the tocopherol/tocotrienol fraction, dihydroxystearic acid and palm-based polyols. Although the components are mainly derived from plants, the palm-based cosmetics are also subjected to various safety and efficacy evaluations to ensure their safe use and to guarantee their efficacy.

ABSTRAK

Ujian keselamatan dan keberkesanan bahan aktif dalam kosmetik atau produk kosmetik penting untuk melindungi keselamatan pengguna dan memastikan pernyataan berbukti. Apabila bahan sintesis atau bahan yang diekstrak semakin banyak dihasilkan untuk industri kosmetik dan dandanan diri, semakin banyak formulasi produk kosmetik baru dapat dihasilkan untuk memenuhi pasaran baru. Perkembangan pesat dalam pembangunan bahan aktif baru dan rumusan produk ini telah meningkatkan permintaan menjalankan ujian keselamatan dan keberkesanan produk. Selain itu, data keselamatan dan keberkesanan produk juga diperlukan oleh pihak berkuasa bagi memastikan industri kosmetik mematuhi peraturan perundangan. Produk kosmetik berasaskan sawit dirumus dengan menggunakan bahan oleokimia dan bahan aktif sawit seperti fraksi tokoferol/tokotrienol, asid dihidroksistearik dan poliol berasaskan sawit. Walaupun komponennya diperoleh daripada tumbuhan, namun produk kosmetik berasaskan sawit perlu juga diuji keselamatan penggunaannya dan juga untuk memastikan keberkesanannya.

Keywords: safety and efficacy evaluations, palm-based cosmetics ingredients, oleochemicals.

INTRODUCTION

Cosmetics are substances used to enhance or protect the appearance or odour of the human body. Cosmetics include skin care creams, lotions, powders, perfumes, lipstick, fingernail and toenail polish, eye and facial make-up, permanent waves, hair colours, hair sprays and gels, deodorants, baby products, bath oils, bubble baths, bath salts, butters and many other types of products. Their use is widespread, especially among women. A subset of cosmetics called decorative cosmetics refer primarily to coloured products intended to alter the user's appearance.

The European Union (EU) Cosmetics Directive 76/768/EEC defines cosmetics as 'any substance or preparation intended to be placed in contact with external parts of the human body (epidermis, hair system, nails, lips and the external genital organs) or with the teeth and mucous membranes of the oral cavity with a view, exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or to keep them in good condition.'

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The cosmetics and personal care industry is one of the potential growth areas identified in the development of oleochemical downstream processing for the production of high value-added products. Basic oleochemicals which are glycerine, fatty acids, fatty alcohols, fatty esters and soaps have significant impact on the cosmetics industry. Oleochemicals are used directly or as intermediate in cosmetics and personal care products as oily bases and emollients. During the last 15-20 years, the cosmetics and personal care industry has shifted quickly from materials from fossil sources as well as adipose towards plant-based oils (Pletnev, 2003).

Meanwhile, the global market for cosmetics and personal care products showed a strong market growth rate of 6% in 2007. Products with claims of being natural account for about 12% of the global market for cosmetics and personal care products (Anon., 2008). In Malaysia, the cosmetics and personal care product market is growing, and the sales of cosmetics and personal care products are growing at an estimated rate of 5% per annum.

Consumers have a tendency to associate natural with plant-derived products, and believe that these are milder and more environmental-friendly than petrochemical or animal-based products. Religious considerations also mean consumers prefer plant-derived products because they are always *kosher* or *halal*. Consumers use cosmetics daily, thus safety and efficacy are important factors that influence the purchase of these products. In a knowledge-based community, information on the safety and efficacy of cosmetics can be retrieved quickly. This rapid development warrants that every cosmetics producer has to focus more on the safety and efficacy of its products.

SAFETY ASSESSMENTS

The provisions of Article 3 of the ASEAN Cosmetic Directive stipulate that a cosmetic product put on the market must not cause damage to human health when applied under normal or reasonably foreseeable condition of use, taking into account in particular of the product presentation, its labelling, instruction for its use and disposal warning statements as well as any other information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the market (Anon., 2010).

Cosmetic products in Malaysia are regulated under the Control of Drugs and Cosmetic Regulations 1984. In conformance with the harmonization of cosmetic regulations in the ASEAN region, cosmetic manufacturers are required to only notify the National Pharmaceutical Control Bureau (NPCB) of their compliance to the ASEAN Cosmetic Directive. NPCB has an active role in conducting post-market surveillance to ensure compliance, and action will be taken against the manufacturer of any product that does not comply with the Directive.

The ASEAN Guidelines for Safety Evaluation of Cosmetics (Annex I, Part 6) require the documentation of all safety data to be compiled as a Product Information File (PIF). As far as the skin is concerned, the two main untoward reactions to be avoided are skin irritation and skin sensitization. Products applied on the scalp or the face may come in contact with the eye. Consequently, eye tolerance has to be addressed with optimal attention being a major component of the safety assessment for such cosmetic products. Ensuring the safety of a cosmetic product requires a global approach throughout the life of the product: from the choice of the raw materials to the marketing follow-up. A number of issues have to be taken into account, including:

- applying Good Manufacturing Practice guidelines for cosmetics (ASEAN Cosmetic Directive - Technical Documents) or approved equivalent;
- careful selection of the cosmetic ingredients, making sure that they will be safe at a given concentration in a given finished product;
- checking local tolerance of the finished product (ASEAN Guidelines for safety evaluation of cosmetic products);
- selection of adequate packaging to maintain the quality of the product and to avoid, as far as possible, risks of misuse or accident;
- quality control, mainly microbiological and chemical;
- stability studies, *e.g.* to evaluate shelf-life, preservative effectiveness (challenge test); and
- appropriate labelling – presentation of the product, instructions for use and disposal, warnings (if relevant) and appropriate action required in case of accident.

Table 1 shows the tests for safety assessment of cosmetics and personal care products provided by the Malaysian Palm Oil Board (MPOB).

As mentioned above, the two main untoward reactions to be avoided in cosmetics are skin irritation and skin sensitization. These reactions can be evaluated via *in vitro* and *in vivo* skin irritation and sensitization testing (*Figure 1*) of the raw materials or end products.

Palm-based Dihydroxystearic Acid as a Cosmetic Ingredient

Palm-based dihydroxystearic acid (DHSA) is derived from palm oil-based or palm kernel oil-based oleic acid by catalytic reaction (Roila *et al.*,

TABLE 1. TESTS FOR SAFETY EVALUATION OF COSMETICS AND PERSONAL CARE PRODUCTS

Test	Details
Patch test	Evaluation for skin irritation
Human repeated insult patch test (HRIPT)	Evaluation for cumulative irritation and allergic reactions
Repeated application	Evaluation for changes in skin properties due to rinse-off product application
In vitro ocular irritection assay	*In vitro* assessment of ocular irritation potential of active ingredients or products
In vitro dermal irritection assay	*In vitro* assessment of dermal irritation potential of active ingredients or products

Figure 1. Safety assessment test: in vitro *irritection assay (left) and* in vivo *patch test (right).*

2001). A patent (PI20050240041) has been awarded to MPOB on the preparation of palm-based hydroxystearic acid (Salmiah *et al*., 2005). This fatty acid has a unique structure with two vicinal alcohol groups and a reactive carboxylic group, which can lead to many interesting applications.

In cosmetics, DHSA can change the properties of the oily phases and wax gels significantly. Moreover, it interacts strongly with the solid surfaces of pigments and inorganic fillers, leading to colour enhancement, long-lasting skin adhesion and better pay-off. Full development work has been applied to its properties in make-up products and emulsions (Rigano, 2003; Rosnah *et al*., 2004).

As a potential cosmetic ingredient, safety data for DHSA are vital for its commercialization as such. According to SCCNFP (Scientific Committee for Cosmetic and Non Food Product) of the European Union Commission, several basic requirements must be ascertained before an ingredient or a product can be commercialized (Anon., 2002). The requirements needed to prepare a *dossier* are: chemical identification, physical form, molecular weight, purity, characterization of impurities, solubility, partition coefficient and, *in vitro* and *in vivo* skin irritation and sensitization studies. All requirements except the *in vitro* and *in vivo* studies can be obtained through chemical elucidation and experimentation. The safety assessment of DHSA, particularly the *in vitro* ocular and dermal irritations and *in vivo* skin irritation and sensitization, has been documented (Zafarizal *et al.,* 2006).

In vitro Ocular Irritation Assay

The evaluations were carried out using two batches of DHSA, compared against sodium lauryl sulphate (SLS), which is a known skin irritant. *Figure 2* shows the results of the *in vitro* ocular irritation assays of DHSA and SLS samples. Both DHSA samples, S2 and S3, showed irritation draize equivalent (IDE) scores of 8.3 and 15.8, respectively, while SLS had an IDE score of more than 25. Chemicals with IDE scores of more than 30 and 51 are classified as moderate or severe irritants, respectively. Based on these data, both DHSA samples were classified as having no or minimal irritation potential while SLS was classified as having mild to moderate irritation potential.

In vitro Dermal Irritation Assay

Figure 3 shows the results of the *in vitro* dermal irritation assays of four DHSA samples and with

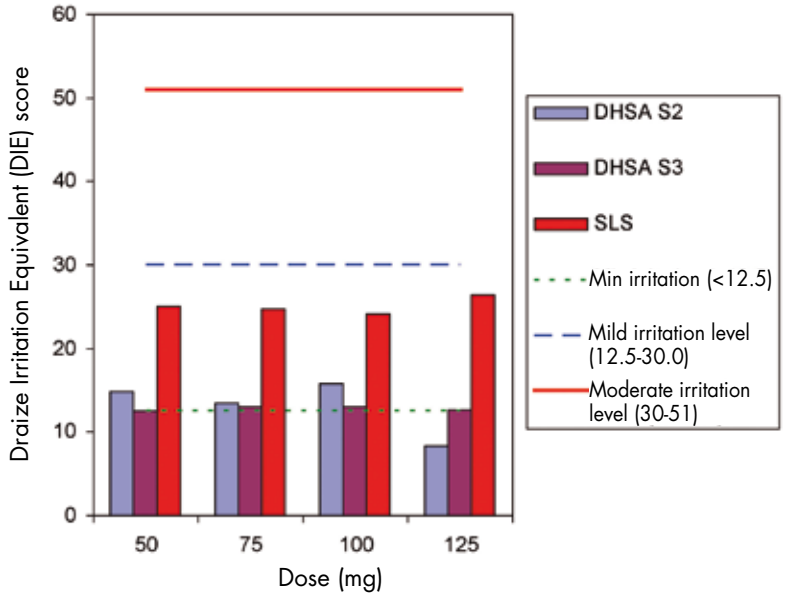

Figure 2. Draize Irritation Equivalent score of dihydroxystearic acid (DHSA) vs. *sodium lauryl sulphate (SLS).*

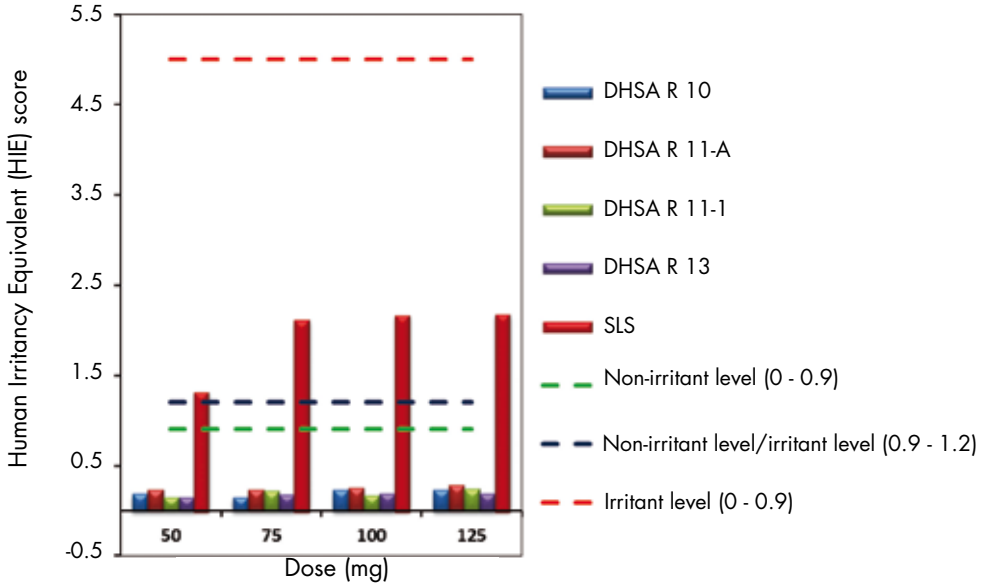

Figure 3. Human Irritancy Equivalent score of dihydroxystearic acid (DHSA) vs. *sodium lauryl sulphate (SLS).*

SLS for comparison. All DHSA samples showed human irritation equivalent (HIE) scores of between 0.15 and 0.28, which are below the non-irritant level. The range indicated that all DHSA samples could be classified as being non-irritant while the SLS HIE score was higher than for the irritant level and was thus classified as an irritant.

In vivo Patch Test

All patch test reactions and scores adopted the method according to Rieche *et al.* (1998) who also followed the International Contact Dermatitis Research Group (ICDRG), which had defined the protocol for evaluating erythema. In this study, the DHSA sample was dispersed into petroleum jelly at concentrations of 1%, 3% and 5%. In the study, the samples were patched on the back of 20 subjects, all males, aged between 18 and 45 years old (average age: 31.6 years), with good health and free from skin infections. At least 20% of the selected subjects needed to have elicited a certain degree of cutaneous reaction to skin care products in the past. The samples were patched for 48 hr and clinical evaluations were carried out after patch removal. The results in *Figure 4* indicate that DHSA at 1%, 3% and 5% concentrations did not induce any irritation reaction at 48 and 96 hr after patch removal. Similar

observations were recorded for the control sample (petrolatum) and the control container of empty Finn chamber (EFC). The positive control was SLS at 0.5% for which intense erythema with bullae was observed in most cases. SLS is a known chemical skin irritant and is used in human studies as a positive patch and as a skin irritation model (Lee and Maibach, 1995). In this study, SLS recorded total skin reaction scores of 44 and 32 at 48 and 96 hr after patch removal, respectively, indicating its high irritant potential.

In vivo Human Repeated Insult Patch Test (HRIPT)

HRIPT is used to determine the incidence and severity of cumulative irritation and allergic contact dermatitis by the use of predictive patch test techniques. Repeat patching with the test material has been shown to produce both cumulative irritation and allergic contact dermatitis. A total of 25 subjects, aged between 23 and 50 years (average age: 30 years), with good health and free from skin diseases, took part in the study. The demographic breakdown was 19 Malay subjects and six Chinese subjects. They were clearly informed of the study and the possible risks related to it. However, after the second and fifth days of the induction phase, three subjects dropped out of the study as they developed adverse skin reactions. Subsequent investigations confirmed that these subjects were allergic to the tape used to secure the Finn chambers and not to the respective samples. Further induction and challenge phases were carried out on the remaining 22 subjects.

After the induction phase, all test samples except for the 0.5% SLS sample showed total cumulative scores of ≤ 10 (*Figure 5* and *Table 2*) which is in category I of the Berger and Bowman Classification. These materials were therefore considered mild and there was no evidence of cumulative irritation under the conditions of tests, *i.e* DHSA at 1%, 3% and 5%. SLS at 0.5% recorded a total cumulative score of 713, which is in category IV indicating evidence of a higher potential for mild to moderate cumulative irritation at 0.5%. The very high cumulative irritation score of SLS acquired under this study also substantiated the claim that SLS is a strong irritant at 0.5% concentration and is in agreement with findings by other investigators (Lee and Maibach, 1995).

After the induction phase, the test subjects were rested for two weeks. A single challenge patch with DHSA at 1%, 3% and 5% was then applied on a different site for 48 hr, and readings were made 48 hr and 96 hr after removal of the patch. The results showed transient reactions after 48 hr and 96 hr (*Table 3*). Normally, allergic reactions do not improve markedly at 72 to 96 hr. However, the challenge patch test on DHSA at 1%, 3% and 5% did not record any significant cutaneous reaction. No expression of irritation or allergic reaction was ob-

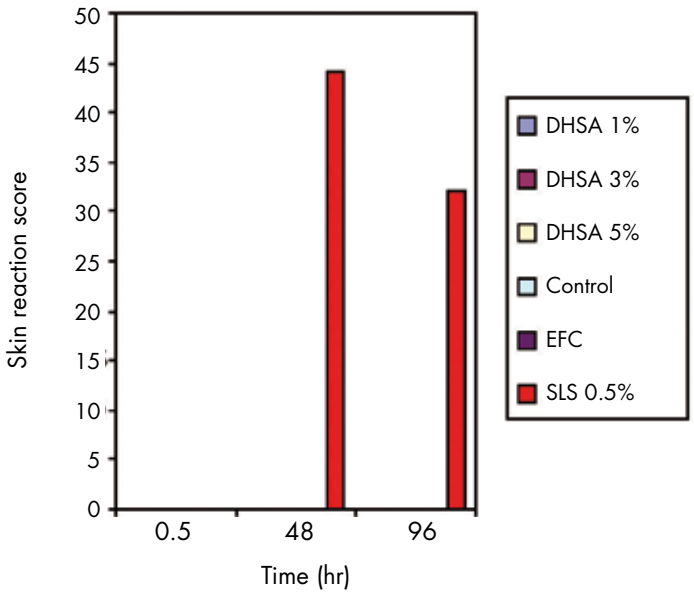

Figure 4. Patch test score of dihydroxystearic acid (DHSA) at 1%, 2% and 3% against a control and 0.5% sodium lauryl sulphate (SLS).

TABLE 2. INTERPRETATION OF TOTAL CUMULATIVE SCORES OF DIHYDROXYSTEARIC ACID (DHSA) AT 1%, 3% AND 5%, BLANK FINN CHAMBER AND PETROLATUM

Sample	Total cumulative score	Classification	Remark
Blank Finn chamber	10	1	Mild
Petrolatum	4	1	Mild
DHSA 1%	4	1	Mild
DHSA 3%	4	1	Mild
DHSA 5%	3	1	Mild
0.5% SLS	713	4	Irritant

TABLE 3. RESULTS OF CHALLENGE PATCH TEST FOR DIHYDROXYSTEARIC ACID (DHSA) AT 1%, 3% AND 5%

Reaction score	Subjects with reaction after 48 hr	Subjects with reaction after 96 hr
0	21	23
0.5	1	0
1	1	0

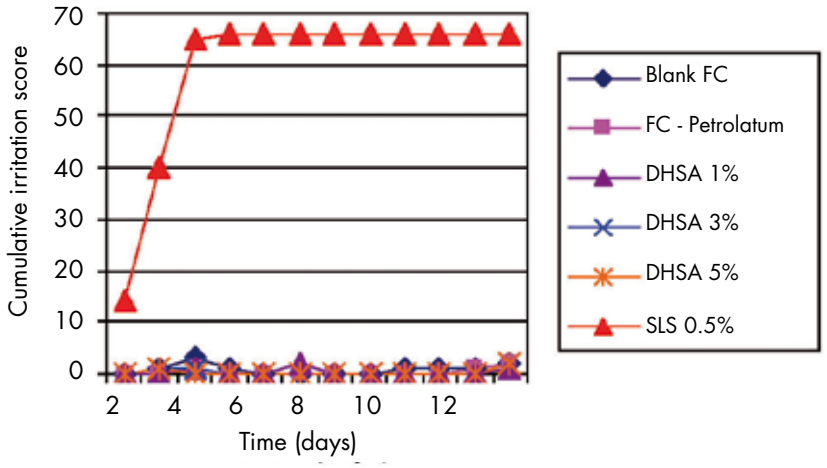

Figure 5. Total cumulative potential of blank Finn chamber, petrolatum, dihydroxystearic acid (DHSA) 1%, DHSA 3% and DHSA 5% and sodium lauryl sulphate (SLS) at 0.5%.

served among the test subjects during this procedure.

The results indicate that the DHSA preparations at 1%, 3% and 5% did not produce irritant contact dermatitis or cumulative skin irritations.

EFFICACY EVALUATIONS

Safety evaluation must be carried out on new raw materials as well as on newly formulated products to ensure that they are safe for use. Besides safety data, the cosmetics manufacturer must also ensure and compile efficacy data to substantiate any claim. The company or person placing a cosmetic product in the market must be responsible for ensuring its safety, quality, performance or efficacy, and must ensure that the product complies with all existing regulations. A cosmetic claim is a benefit that is perceived by a consumer when using a decorative, cosmetic, hair or skin care product. Global regulatory governance dictates that cosmetic claims need to be substantiated to support all the claims given to a product. Objective substantiation

of claims for cosmetic products is an area of continuing interest within the cosmetics industry, and support of claims for cosmetic products has to be based on scientific evidence. Obviously, there is a need to protect the consumer from misleading advertisements, because excessive claims lead to doubt and they impact unfairly on companies making justifiably substantiated product claims.

The main function of skin care products is to improve the appearance and feel of the skin. Recent developments in skin bioengineering techniques enable various tests for assessment of product efficacy on the skin. Tests for moisture content, moisture transmission, viscoelastic response, ultrasound, laser doppler imaging and electrical properties of the skin have been developed with the introduction of various skin bioengineering instruments. Many efforts have been made in skin research to develop *in vitro* methods for efficacy testing of products as a means to reduce or replace animal testing (*Figure 6*). Most of these new tests have evolved to help evaluate the performance of products, to screen formulations and to determine the effective level of the active ingredients. The range of efficacy studies that can be carried out for claim substantiation of cosmetics and personal care products which are available at MPOB are listed in *Table 4*.

Palm Tocotrienol-rich Fractions

Safety assessment of palm tocotrienol-rich fractions (TRF) has been carried out, and the results indicate that palm TRF do not induce any cutaneous irritation or sensitization (Zafarizal *et al.*, 2008). The results prove that palm TRF can be incorporated into cosmetics and personal care products without inducing any side reactions to the skin. Topical application of palm TRF up to 5% has been demonstrated to protect the skin against ultraviolet (UV) radiation. Studies on UV-induced skin inflammation have demonstrated the photoprotective effects of palm TRF, suggesting their anti-inflammatory properties. This result is shown in *Figure 7*. The effect of post-treated TRF on ultraviolet B (UVB)-induced skin erythema was also studied. Results given in *Figure 8* indicate that TRF has the potential to reduce photo-damage to the skin if it is applied immediately after UVB radiation. The percentage of inhibition as shown by mean chromametry readings was between 28% and 31%. This result indicates that TRF had effectively reduced the skin erythema. It was also noted that a combination of antioxidants, TRF and vitamin C, resulted in a higher suppression of UVB-induced skin erythema than when using TRF alone (Zafarizal, 2003; Zafarizal *et al*., 2009).

TABLE 4. EFFICACY EVALUATION ON COSMETICS AND PERSONAL CARE PRODUCTS

Test	Details
Moisturizing test	Assessment of acute and long-term hydration
Skin pH	Evaluation of skin pH
Skin sebum	Determination of skin sebum level
Transepidermal water loss	Evaluation of skin transepidermal water loss rate
Skin calorimetry	Assessment of skin colour
Skin blood flowmetry	Evaluation of skin micro blood flow
In vivo SPF	Evaluation of sun protection factor according to COLIPA's method
In vivo SPF (water resistant)	Evaluation of sun protection factor of a sunscreen with water-resistant properties
Skin elasticity	Determination of skin elasticity
Skin barrier effect	Evaluation of product efficacy in protecting the skin
Skin barrier recovery	Evaluation of product efficacy in skin's recovery properties
Anti-stretch mark	Evaluation of product efficacy in reducing appearance of stretch-marks
Anti-wrinkle	Assessment of anti-wrinkle product in reducing wrinkles or fine lines
Cell renewal	Determination of exfoliating properties by means of dansyl chloride
Skin whitening	Evaluation of product that improves skin colour
Anti-cellulite	Evaluation of product that can reduce cellulitis
Anti-acne	Determination of product efficacy in reducing acne or comedones
Anti-hair loss	Evaluation of anti-hair loss product via phototrichogram
Anti-dandruff	Evaluation of dandruff scales weight, D-Squame and imaging techniques
Slimming test	Evaluation of slimming product via circumference, micro bloodflow and elasticity measurements
Acute vasodilation test	Determination of product efficacy in increasing skin micro bloodflow
Anti-crack heel test	Evaluation of anti-crack heel product by measuring skin hydration, skin roughness and image analysis

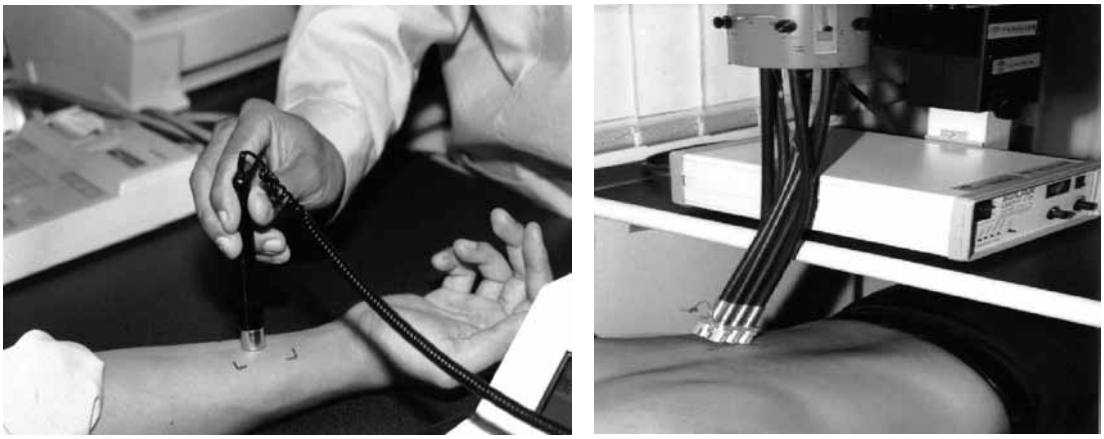

Figure 6. Efficacy assessment test: skin hydration and in vivo *SPF test.*

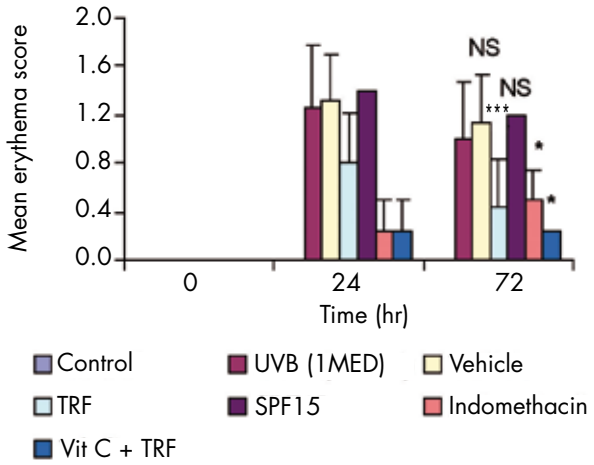

*Figure 7. Mean erythema scores of UVB-induced inflammation reactions on skin treated with a control cream (vehicle), palm TRF cream (TRF), sunscreen with SPF 15 (SPF 15), indomethacin cream (Indomethacin) and cream with vitamin C and palm tocotrienol-rich fractions (TRF) (vit C + TRF). NS - not significant (P>0.05), * - significant (P<0.05), *** - significant (P<0.001).*

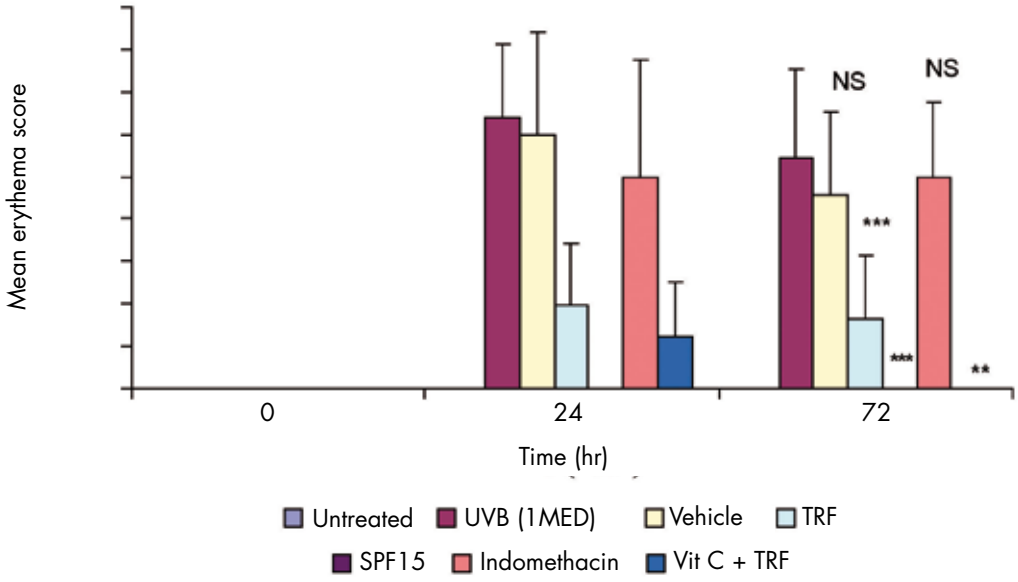

*Figure 8. Mean erythema scores of UVB-induced inflammation reactions on skin pre-irradiated with UVB and treated with a control cream (vehicle), palm tocotrienol-rich (TRF) cream, sunscreen with SPF 15 (SPF 15), indomethacin cream (Indomethacin) and cream with vitamin C and palm TRF (vit C + TRF). NS - not significant (P>0.05), ** - significant (P<0.01), *** - significant (P<0.001).*

Palm-based cosmetic products formulated with palm TRF have the ability to moisturize the skin by increasing skin hydration, and a single dose application of the cream can maintain skin hydration for up to 3 hr as shown in *Figure 9*. Long-term applications of tocotrienol creams have also been shown to enhance skin hydration up to 14 days compared to a placebo (*Figure 10*). The increase in skin hydration is further supported by a reduction in transepidermal water loss (TEWL).

CONCLUSION

Safety and efficacy assessments are important criteria for the commercialization of any cosmetic product. The safety of an ingredient or end-product is of paramount importance to the consumer. Product efficacy with proper claim substantiation based on scientific grounds is an added advantage in a very competitive industry like cosmetics. Palm-based ingredients for cosmetics and palm-based cosmetic products have proven to be safe and are able to exert objective desired changes to skin properties.

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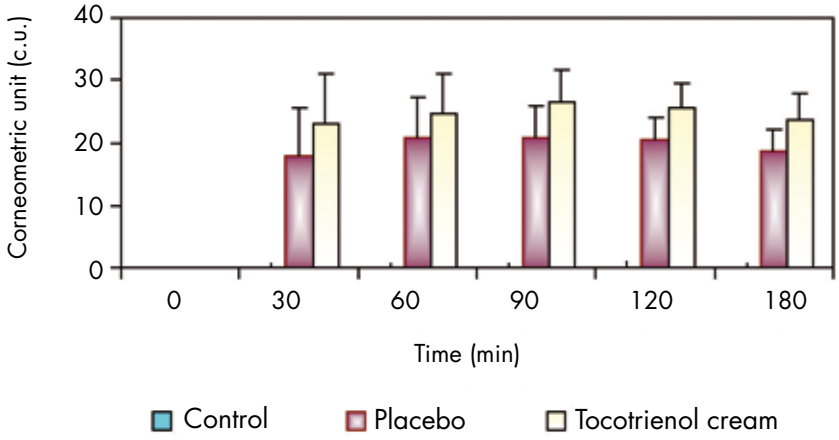

Figure 9. The acute effect of tocotrienol cream on skin moisture.

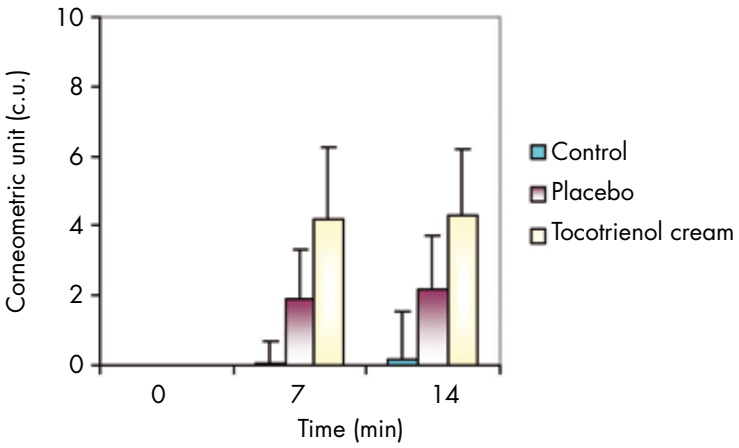

Figure 10. The long-term effect on tocotrienol cream on skin moisture.

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