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Review on Formulation and Evaluation of Sunscreen

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Abstract: *Sunscreen plays a crucial role in protecting the skin from harmful ultraviolet (UV) radiation, which can lead to sunburn, skin damage, and an increased risk of skin cancer. This article explores the various factors influencing sunscreen efficacy, including the significance of SPF (Sun Protection Factor) and the active ingredients used in formulations. SPF calculation is detailed, emphasizing the importance of applying the recommended amount of sunscreen to achieve the desired level of protection. Additionally, the article examines the health risks associated with certain chemical filters, such as oxybenzone and avobenzone, which have raised concerns regarding their systemic absorption and potential hormonal effects. Conversely, the benefits of sunscreen in preventing skin cancer and premature aging are highlighted. It also includes key safety concerns, environmental effects & application of sunscreen.The article also addresses the need for ongoing research to evaluate the safety and efficacy of both chemical and physical sunscreen ingredients, ultimately advocating for informed sunscreen use to maximize skin protection while minimizing health risks.*

Keywords: Sunscreen, SPF, UV, technology

I. INTRODUCTION

Sunscreen, also called sunblock, sun lotion, or sun cream, is a topical product that protects the skin from the sun and helps prevent skin cancer. It is available in various forms, including lotions, sprays, gels, foams, sticks, powders, and other topical applications.[1]Sunscreens primarily protect the skin from both short-term and long-term effects of ultraviolet radiation. In today's procedure-centered dermatology, they are essential for every patient's post-procedure skincare routine.This review conducts a thorough literature survey on the effectiveness and safety of existing chemical, physical, and hybrid UV filters in topical sunscreens. It comprehensively examines the properties, safety, health, and environmental concerns of various sunscreen brands, along with classifications, photoprotection indices, and key issues related to sunscreens.[2]

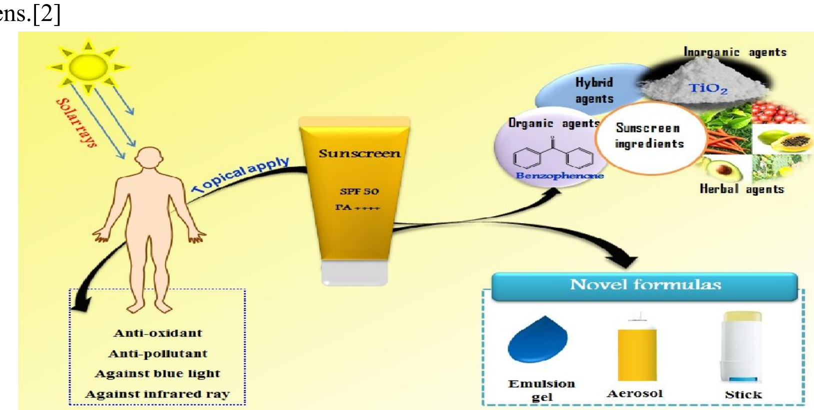

Figure 1 : Details of Sunscreen

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1.A Combination of physical and chemical agent 2.Broad spectrum cosmetically elegant 3.Substantive 4.Non-irritant 5.Hypo allergic 6.Non comedogenic
Table 1: Characteristics of an ideal sunscreen

CATEGORIES OF SUNSCREEN

Sunscreen ingredients protect your skin from UV rays and fall into two categories:

1.Physical Sunscreen

These contain minerals like titanium dioxide or zinc oxide, which are finely crushed and sit on the skin's surface, reflecting UV rays away like a shield. Products with these physical blockers are often referred to as mineral creams or sunscreens.[4]

1. Photostable Filter: This filter dissipates the absorbed energy as heat, returning to its original state and is capable of absorbing UV energy again.
2. Photounstable Filter: This filter changes its chemical structure or degrades after absorbing UV energy, making it unable to absorb UV energy again.
3. Photoreactive Filter: In its excited state, this filter interacts with surrounding molecules, including other sunscreen ingredients, oxygen, and skin proteins and lipids, leading to the production of reactive species that may have undesirable biological effects.

Organic sunscreens are further divided into UVB and UVA filters:

1. UVB filters

PABA Derivatives: Padimate O
Cinnamates: Octinoxate, Cinoxate
Salicylates: Octisalate, Homosalate, Trolamine Salicylate
Other Ingredients: Octocrylene, Ensulizole

2. UVA filters

Benzophenones (UVB and UVA2 absorbers) - Oxybenzone, Sulisobenzone, Dioxybenzone
Avobenzone or Parsol 1789 (UVA1 absorber)
Meradimate (UVA2 absorber)
Note: Avobenzone is the only sunscreen agent with its absorption peak in the UVA1 spectrum (357 nm), making it an effective UVA filter, but it is photounstable. This issue can be mitigated by adding photostabilizing agents to the formulation, including UVA filters like oxybenzone, UVB filters such as enzacamene (not yet FDA approved), salicylates, octocrylene, broad-spectrum filters like bemotrizinol (also not FDA approved), and inorganic filters like titanium dioxide and zinc oxide.

3. Newer generation broad spectrum (UVA + UVB) filters - Ecamsule (Mexoryl SX), Silatriazole (Mexoryl XL), Bemotrizinol (Tinosorb S), Bisoctrizole (Tinosorb M). [3]

2. Hybrid sunscreens, which contain a combination of organic and inorganic UV filters.As of 2021, only zinc oxide and titanium dioxide are recognized as safe and effective (GRASE) by the U.S. Food and Drug Administration (FDA), as there is not enough data to deem petrochemical UV filters safe. [10]

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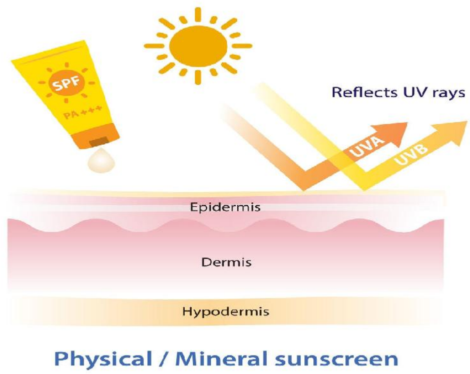

Figure 2: Mineral Sunscreen

3. Chemical sunscreen

The chemicals in sunscreens create a thin protective layer that absorbs UV rays before they can penetrate the skin. Sunscreens containing chemical absorbents are often referred to as organic sunscreens, and they may also be called petrochemical sunscreens because their active organic molecules are typically synthesized from petroleum-derived building blocks.[5] These chemicals primarily work by absorbing UV rays.[6] However, some organic UV absorbers have faced scrutiny over their toxicity,[7] leading to bans in countries like Hawaii[8] and Thailand [9] due to their harmful effects on aquatic life and the environment.The two types of sunscreen ingredients have their own advantages and disadvantages. Physical sunscreens typically do not cause irritation, hives, or allergic reactions, but they can leave a white, greasy residue. In contrast, chemical absorbent sunscreens are usually clear and easy to apply, but they are more likely to cause irritation and allergic reactions. Many sunscreens combine physical and chemical inhibitors to maximize benefits and minimize drawbacks. Additionally, a broad-spectrum sunscreen often requires a combination of ingredients to protect against both UVA and UVB rays that can cause skin damage.[4]

SPF - Sun Protection Factor

SPF is a measure of the amount of solar energy (UV radiation) required to cause sunburn on protected skin (i.e. in the presence of a sunscreen) compared to the amount of solar energy required to cause sunburn in the unprotected skin. As the SPF value increases, the sun protection increases.Many consumers mistakenly believe that SPF indicates how long they can stay in the sun. For instance, some think that an SPF 15 sunscreen allows them to stay in the sun for 15 hours if they normally get sunburned in one hour. However, SPF is not directly linked to time but to the level of sun exposure. While the duration in the sun is related to solar energy, other factors, such as the intensity of solar energy, also influence exposure levels.The following exposures can produce the same amount of solar energy: •One hour at 9:00 am. •15 minutes to 1 p.m. [11]

PA INDEX

The PA index, established by the Japan Cosmetics Association, measures a sunscreen's protection against UVA rays. It is derived from the PFA (Protection Factor of UVA), which is calculated based on the minimum UVA dose that causes melasma 2-4 hours after sun exposure. Most sunscreens now offer long-lasting UVA protection, with PA++ providing coverage for 4-8 hours. [12]

Sunscreen Regulations

Sunscreens are typically assessed using one of the following methods and must meet labeling requirements according to the guidelines of each country.

- **US-FDA Method:** The FDA evaluates sunscreens by measuring in-vitro UV transmittance through a sunscreen film using the critical wavelength method. Products that primarily protect against UVB have a critical wavelength below 320 nm, while those offering both UVA and UVB protection fall between 320 and

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400 nm. To qualify as "broad-spectrum" and provide effective UVA and UVB protection, the sunscreen must have a critical wavelength of at least 370 l (mean value). [13]

- **UK (Boots Star Rating):** The Boots star rating system in the UK assesses UV transmittance through a sunscreen layer applied to abraded PMMA plates. It calculates the ratio of mean UVA to UVB absorbance before and after the sunscreen is irradiated. [14]
- **Australia (AS Method):** The Australian standard employs a spectrophotometer to measure the amount of solar radiation a sunscreen transmits. A sunscreen qualifies as a long-wave protector only if it allows less than 10% transmission of UV radiation within the 320–360 nm range.
- **European Countries (COLIPA Guidelines):** COLIPA, a voluntary association within the cosmetics industry, aims to standardize sunscreen labeling and testing across Europe. Its guidelines are primarily for liquid and emulsion sunscreens. UVA protection is evaluated by measuring UV transmittance through a 0.75 mg/cm² thin sunscreen film on a roughened substrate, before and after exposure to controlled UV radiation. In-vitro UVAPF values derived from this method closely match in-vivo results obtained using the PPD method. [15]
- **International Organization for Standardization (ISO):** The ISO, an independent global organization headquartered in Geneva, consists of 162 national standards bodies. It plays a key role in developing international standards for sunscreen testing and labeling. [16]ISO Methods for Sunscreen Evaluation
- **ISO 24443:2012:** This standard outlines an in-vitro method for assessing UVA protection in sunscreen products. It provides guidelines to measure the spectral absorbance of UVA in a consistent way. The procedure generates a UV spectral absorbance curve, which allows for various calculations and evaluations. It relies on in-vivo SPF results to calibrate the UV absorbance curve.
- **ISO 24442:2011:** This standard describes an in-vivo method to determine the UVA Protection Factor (UVAPF) of sunscreen products. It applies to cosmetics, drugs, and other products used on human skin that can absorb, reflect, or scatter UV rays. The standard serves as a foundation for evaluating sunscreen effectiveness against UVA radiation from sunlight or artificial light sources.
- **ISO 24444:2010 :** This standard specifies an in-vivo method for determining the Sun Protection Factor (SPF) of sunscreen products. It applies to products containing components that can absorb, reflect, or scatter UV rays and are meant for use on human skin. The standard provides a framework for assessing sunscreen effectiveness in protecting against erythema caused by UV rays. [17]

Sunscreen Evaluation in Different Countries

- **India :** As part of the Asian population with predominantly Type IV skin, which burns minimally and tans easily, sunscreen use in India is crucial to prevent tanning. Sunscreens are classified as cosmetics under the Indian Drug and Cosmetic Act (1940), updated periodically. The Bureau of Indian Standards (BIS), an ISO member, establishes product standards, including stability requirements similar to those in Australia. There is no upper limit on SPF ratings.
- **Japan :** The Japan Cosmetic Industry Association (JCIA) follows self-regulated standards and aligns with ISO and COLIPA International SPF testing methods. ISO 24444 is used for SPF evaluation. For UVA, in-vivo testing is mandatory, and labeling follows the Protection Grade of UVA (PA) system (PA+, PA++, PA+++, and PA++++ introduced in 2013).
- **China :** Sunscreen regulations fall under the Hygienic Standard for Cosmetics 2007. Sunscreens are capped at SPF 30+ for labeling and must include Chinese-language labels. Water resistance claims must adhere to specific norms if stated on the product. [18]

ACTIVE INGREDIENTS

1. **Tinosorb S and M :** Tinosorb S, a common ingredient in European chemical sunscreens, protects against both UVB and UVA rays and helps stabilize other filters. Although it can be used in concentrations up to 10%, the FDA hasn't approved it, citing a "lack of information." Tinosorb S is added to sunscreens to enhance effectiveness and has no known high-risk factors.

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2. **Mexoryl SX :** Mexoryl SX is a UV filter used in sunscreens worldwide, known for blocking UVA1 rays that cause skin aging. A 2008 review confirmed its effectiveness in preventing sun damage. Although used in Europe since 1993, the FDA approved it for L'Oréal in 2006. It's safe for adults and children over 6 months. Combined with avobenzone, it enhances and stabilizes UVA protection.
3. **Oxybenzone :** Oxybenzone, a common ingredient in broad-spectrum sunscreens, filters both UVB and short UVA rays, and can make up to 6% of a sunscreen formula. However, it has been banned in Hawaii due to its role in coral reef bleaching. Though recent studies show that oxybenzone is absorbed by the skin, no harm has been found, and it does not significantly disrupt the endocrine system. For environmental reasons, many prefer "green" sunscreens without oxybenzone.
4. **Octinoxate:** Octinoxate, a powerful UVB absorber, helps prevent sun damage and, when combined with avobenzone, offers strong broad-spectrum protection. While allowed in formulations up to 7.5%, it is banned in Hawaii due to its environmental impact on coral reefs.
5. **Avobenzone:** Avobenzone is widely used to block UVA rays but is unstable on its own when exposed to light. It's often paired with ingredients like Mexoryl to stabilize it. In many countries, it's combined with zinc oxide or titanium dioxide, though this mix isn't allowed in the U.S. Avobenzone loses 50-90% of its effectiveness within an hour of sun exposure, so it's typically combined with other chemicals. The FDA considers it safe in the U.S., with a concentration limit of 3% in sunscreens.
6. **Titanium dioxide:** The FDA recognizes two physical sunscreen ingredients as safe and effective (GRASE), meaning they aren't closely monitored. One is titanium dioxide, a broad-spectrum UV filter that doesn't block long UVA1 rays. Approved for use in children over 6 months, it's generally safer via skin exposure. However, powder and spray forms should be avoided due to potential hazards. While oral exposure to titanium dioxide nanoparticles is "possibly carcinogenic" in animals, it's also found in SPF makeup, powders, lotions, and whitening products.
7. **Zinc oxide:** Zinc oxide is the second GRASE sunscreen ingredient, permitted in concentrations up to 25%. Studies show it's safe, with no evidence of skin penetration even after repeated use. However, it is labeled with a warning in Europe due to its toxicity to aquatic life and poses risks only if swallowed or inhaled. Compared to avobenzone and titanium dioxide, zinc oxide is considered photostable and safe for sensitive skin, but research indicates it may not be as effective as chemical sunscreens for sunburn protection.

1. **8 and 9. PABA and trolamine salicylate PABA:** Para-aminobenzoic acid (PABA) is a strong UVB absorber found in both chemical and physical sunscreens, but its popularity has declined due to its association with allergic dermatitis and increased photosensitivity. Animal studies have shown potential toxicity, prompting the FDA and European Commission to limit its concentration to 5%, while Canada has banned it in cosmetics. Trolamine salicylate (Tea-Salicylate) was deemed GRASE in 2019, but research indicates it's a weak UV absorber, so its use is limited alongside other GRASE ingredients. [19]

ULTRAVIOLET RADIATION

Ultraviolet (UV) radiation is a type of energy produced by the sun and by artificial sources, such as tanning beds. UV radiation is the main cause of melanoma and other skin cancers such as basal cell carcinoma and squamous cell carcinoma.The sun's UV rays can reach a person three ways: directly from the sun; scattered from the open sky; and reflected by the environment. The radiation level depends on a number of factors:

Types of UV rays

There are three types of UV radiation from the sun: UVA,UVB, and UVC. All can cause skin and eye damage.

UVA (320-400 nm) is the most abundant but least potent UV radiation, making up 95% of the UV light we encounter. It doesn't contribute to vitamin D production but can penetrate clouds and car windows, exposing us year-round. UVA penetrates deep into the skin, leading to wrinkles, leathering, and premature aging.

UVB (290-320nm) is the second most potent type of UV radiation. It penetrates the top layer of the skin and is the primary cause of sunburns (remember "B" for burns). UVB is the main cause of basal cell and squamous cell carcinoma as well as melanoma.

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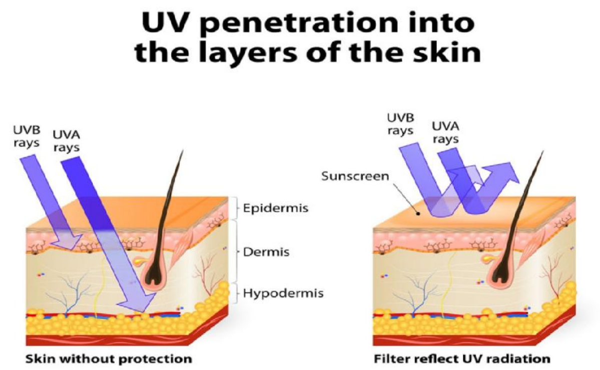

Figure 3 : Effect of UV Rays

UVB is crucial for vitamin D production in the skin, and most people get enough incidental sunlight to meet their vitamin D needs, even with sunscreen use. Certain foods can also provide vitamin D.

UVC (100-290) is the most dangerous type of UV radiation, but fortunately, the sun's UVC is absorbed by our atmosphere before it reaches the earth's surface. However, there are other sources of UVC, such as in arc welding, from which workers need to protect themselves with face-shields, protective clothing, and eye protection.

Check Your Local UV Index : Enter your city or zip code and see what your current UV index is for your location.[20]

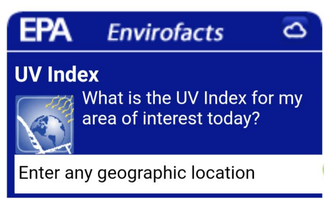

Figure 4 : UV Index

II. RECOMMENDATIONS FOR SUNSCREEN APPLICATION

Sunscreen should be applied evenly to all sun-exposed areas at a concentration of 2 mg/cm² and allowed to dry completely before sun exposure. It should be reapplied every two hours, as well as after swimming, vigorous activity, excessive sweating, or towel drying.

Teaspoon Rule: [21]

3 mL (just over half a teaspoon) for each arm

3 mL for the face and neck

6 mL (slightly more than a teaspoon) for each leg

6 mL for the chest

6 mL for the back

Debatable Issues

1. Sunscreen Use in Infants: Sunscreens are not recommended for infants under 6 months, although they are not considered hazardous.[22]
2. Contact Dermatitis: Oxybenzone is the most common cause of contact dermatitis (photoallergy) associated with sunscreens.[22]
3. Nanosized Particles: Nanosized particles (1-100 nm), such as microfine zinc oxide and titanium dioxide (20-50 nm), enhance the cosmetic appeal of inorganic sunscreens by reducing skin whitening.[23]

4. Vitamin D Production: UVB radiation is responsible for over 90% of vitamin D production in the skin. While high SPF sunscreens can reduce vitamin D production in controlled settings, normal use does not generally lead to vitamin D deficiency, [24]as seen in patients with xeroderma pigmentosum.[25]
5. Hormonal Effects: Some sunscreens, including oxybenzone and avobenzone, have shown estrogenic and anti-androgenic properties in animal studies. [23]

III. NEW SUNSCREEN TECHNOLOGIES

Chromophore-based sunscreens:

Chromophore-based sunscreens represent a novel sun protection method, using molecules called chromophores to absorb and neutralize UV radiation. These molecules are engineered to selectively absorb UVA and UVB rays, converting them into less harmful energy, like heat.

Antioxidant Integration: Defending Against Free Radicals

UV exposure generates free radicals that accelerate skin aging. Modern sunscreens incorporate antioxidants like vitamins C and E, green tea extract, and ferulic acid to neutralize these radicals, offering additional protection against oxidative damage and enhancing anti-aging effects.

Biodegradable & Reef-Safe Formulations: Eco-Friendly Focus

To minimize environmental impact, new sunscreens are designed with biodegradable and reef-safe ingredients.

Personalized Sunscreen Solutions: Customized Care

Leveraging advances in AI and skin analysis, companies are now offering personalized sunscreen recommendations. This approach considers factors [26]

Nanotechnology: Improving Sunscreen Effectiveness

Nanotechnology has transformed sunscreen by refining nanoparticles of titanium dioxide and zinc oxide. This innovation minimizes the whitening effect while maintaining strong UV protection. These nanoparticles also boost stability and water resistance, ideal for extended outdoor use.

Encapsulation, Controlled release Technology: Enhancing Ingredient Delivery

Encapsulation involves enclosing UV filters and active ingredients in tiny capsules, allowing for controlled release that boosts efficacy and stability.

Waterless Sunscreen

L'Oréal has developed a waterless sunscreen using liquid carnauba wax, reported by Cosmetics Design-Europe on August 13. The formula includes an oil-in-water carnauba wax, silica aerogel, and UV filters to address challenges of anhydrous sunscreens, as noted in its international patent.[27]

UV- Sensing with colour changing sunscreen

In real-world settings, sunscreen is frequently under-applied or not reapplied adequately to ensure effective protection. This field study evaluated the effectiveness of UV detection stickers in reducing sunburn and promoting better sunscreen reapplication. [28]

IV. BENEFITS

Using sunscreen protects against harmful ultraviolet (UV) rays, helping to prevent skin cancer, which can affect anyone regardless of age, gender, or skin tone. Additionally, sunscreen helps prevent premature skin aging, including wrinkles and age spots, caused by excessive UV exposure without protection. [29]

Sunscreen Formulations

1. Emulsion Formulation

An emulsion is called a lotion or cream based on its viscosity, which is less than 50,000 and in the range of 150,000 to 500,000 centipoises respectively, offering almost unlimited versatility. It is usually produced from two immiscible liquid phases, namely water-in-oil and oil-in-water emulsions. These emulsions have the ability to spread more easily on the skin and dispense from bottles18. Emulsion sunscreens also provide an elegant support that can leave the skin smooth and silky without a greasy shine. However, they are very difficult to stabilize, especially at high temperatures [30, 31].

2. Gel Sunscreen

Sun gel seems to represent an ideal vehicle from an aesthetic point of view due to its purity and elegance. It is classified into four main forms, namely aqueous, hydroalcoholic, microemulsion and anhydrous oily formulations [30]. Aqueous gel should be consisting of water and solvents, for example non-ionic surfactants, organic agents and phosphate esters in sufficient quantities to ensure that the gel will be transparent at all temperatures. Therefore, it is easily removed when exposed to water or sweat [32]. Hydroalcoholic gels are formulated from alcohol (ethanol) bound to water, which is important for reducing additional solutions because most lipophilic ingredients mix easily with alcohol. Microemulsion gels are composed of small particles, which allow them to appear smooth, thick, and uniform on the skin, thus ensuring an elegant and high SPF [30, 33]. Anhydrous oil formulations are similar in many respects to ointments. However, anhydrous petroleum products are clear, while ointments are translucent. These products can be made into gels combined with mineral oil and special silica [34] However, they are not widely sold because they are difficult to produce and quite expensive

3. Aerosal Formulation

Aerosol sunscreens are applied directly to the skin to safeguard against harmful sunlight and prevent skin disorders. These products are easy to apply, evenly covering the skin's surface and forming a thin protective layer infused with active ingredients. [35]

4. Sun Stick Formulation

The sun stick is considered one of the most convenient sunscreen products due to its compact size and lightweight design. It is primarily made using two emulsion components: oil and oil-soluble ingredients, combined with petrolatum and waxes. [30] Sun sticks are classified into three types: transparent, semi-transparent, and matte. The transparent variety uses only chemical UV filters, the semi-transparent type combines chemical and mineral substances, and the matte formula consists exclusively of mineral sunscreen ingredients. [36]

Sunscreen Evaluation

In Vivo Evaluation Of Sunscreens

MED (Minimal Erythema Dose) measures the amount of energy per unit area ($J \cdot cm^{-2}$) needed to induce minimal redness on the skin. To validate SPF (Sun Protection Factor) in vivo, an artificial UV source is used on human participants. In Europe, SPF is considered valid if tested on at least 10 subjects.[37]

However, in vivo SPF testing has several limitations. It is costly in terms of both time and money, and it raises ethical concerns about the potential harm to participants' skin. Furthermore, it only measures erythema caused by UVB and UVA-II radiation, so it does not account for protection against the broader UVA spectrum. The significance of adequate UVA protection is becoming clearer as studies show that UVA can damage cellular DNA through interactions with oxygen radicals and endogenous photosensitizers. [38]

Assessing UVA protection in vivo requires high doses of UVA, which presents both economic and ethical challenges. Three methods are proposed to evaluate UVA protection: IPD (Immediate Pigment Darkening), PPD (Persistent Pigment Darkening), and UVA-PF (UVA Protection Factor). IPD measures immediate skin pigmentation changes (seconds), while PPD assesses pigmentation changes that persist for 2–24 hours after UVA exposure.

In-vitro Evaluation Of Sunscreen:

An in vitro SPF testing method would be beneficial if it could provide faster and more affordable results, while also eliminating the ethical concerns associated with in vivo testing. Although several in vitro techniques have been developed, no universally accepted method currently exists. Typically, in vitro methods involve applying sunscreen to an artificial test substrate and using a spectrophotometer to measure the amount of UVR passing through the sunscreen film. Vitro-Skin (IMS Inc.) is a synthetic skin substrate used in these tests, which requires precise hydration procedures.[39]

While Vitro-Skin performs well in sunscreen testing, it has drawbacks, including a high cost per sample, the need for hydration the day before testing, and a relatively short lifespan once hydrated. Biologically derived substrates like excised stratum corneum and human epidermis have also been used, but the results have generally been inconsistent.[40] A recent study [43] correlated in vitro SPF data with values provided by manufacturers. However, the FDA has not yet replaced the in vivo SPF test with an in vitro alternative. [41] One limitation of in vitro tests is the lack of performance data for test substrates such as quartz or artificial skin. In its 2007 rule [42], the FDA concluded that data did not show these substrates could accurately mimic the complex features of human skin. In the 2011 rule [41], the FDA confirmed the exclusion of in vitro tests due to insufficient new data to validate them.

V. CONCLUSION

Sunscreens are essential for protecting skin against harmful UV radiation, preventing sunburn, photoaging, and skin cancer. Advances in formulation science have improved their effectiveness, safety, and user appeal. Organic filters absorb UV rays, while inorganic filters reflect and scatter them, offering complementary benefits. However, challenges like ingredient stability, skin sensitivity, and environmental impact remain. Continuous evaluation ensures the development of safer, more sustainable, and efficient sunscreens. Overall, sunscreen innovation supports both skin health and environmental well-being.

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