**SUNSCREEN: AN INTRODUCTORY REVIEW**

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**ABSTRACT**

Sunscreens are the agents which are used to prevent the skin from the harmful ultraviolet radiation of sun. These agents act as a barrier for the sun rays. Sunscreen can be physical, chemical or natural sunscreen. The effectiveness of sunscreen agents can be measured in terms of Sun Protection Factor (SPF). A sunscreen having SPF value 15 have enough efficacy and products having SPF 15 are widely used. The application of sunscreens also has some harmful effects. Most important is deficiency of vitamin D in the body due to less exposure of the body to sun rays. So sunscreens should be applied in such a manner so that their harmful effects are minimized. The following discussion covers various aspects of sunscreen agents.

**Key words:** Sunscreen, SPF, Colipa method, Sunburn, skin cancer

**INTRODUCTION**

On exposure to sunlight human body experiences both beneficial and harmful effects, depending on the length and frequency of exposure, sunlight intensity and the sensitivity of the individual concerned.

On exposure to sunrays the first effect produced is erythema of skin, followed by formation of tan, which actually is a protective reaction of human body to minimize the adverse and harmful effects of solar radiation. The intensity of erythema [reddening] produced on exposure to sunlight depends on the amount of UV energy absorbed by skin. It usually develops after a latent time period of 2-3 hours and reaches its maximum level within 10-24 hours. The sun emits a wide range of ultraviolet (UV) radiation. All of the harmful UVC (200–280 nm) and most of UVB (280–320 nm) is absorbed by the stratospheric ozone layer. Stratospheric ozone does not affect UVA (320–400 nm) transmission. As the stratospheric ozone layer is depleted the amount of harmful short-wave UV reaching the earth’s surface will increase. On the other hand, chances of UV exposure by increased outdoor activity and imprudent use of sun tanning machines increased the risks of unwanted UV effects, such as sunburn, photo aging, skin cancer induction and immune suppression. Solar UV is the most prominent cause of skin cancer [1].

**Skin and its Anatomy**

Skin is composed of very specific cells and tissues. Figure 1 shows the structure of human skin [2]. The subcutaneous layer of skin contains blood vessels which branch infinitely into the dermis to supply the sweat glands, hair follicles, sebaceous glands and erector muscles with blood. Dermis contains capillaries, which provides the essential nutrients to the cells in the dermis, and also helps the skin to perform cooling function. The epidermis is not supplied directly by blood, but is fed by the dermis. Dermis contains several different nerve endings: heat-sensitive, cold-sensitive, pressure-sensitive, itch-sensitive and pain-sensitive. Epidermis consists of one inner layer, malpighian layer, which creates the dead cells and is in direct contact with the dermis, which feeds and supports it and only it is is affected during sun tanning.

The malpighian layer has a basal layer, a spinous layer, a granular layer, and an outer stratum corneum. The cells in stratum corneum are filled with a protein called keratin. Keratin is a very interesting protein because it is tough - horns, hair, hoofs, fingernails and feathers all gain their strength from keratin. In the basal cells malpighian layer consists cells called melanocytes, which produces melanin, which is a pigment that is the source of tanning. The appearance of the skin is partly due to the reddish pigment in the blood of the superficial vessels and it is determined by melanin, a pigment manufactured by the dendritic cells called melanocytes, found among the basal cells of the epidermis. Colour differences are due solely to the amount of melanin produced and the nature of the pigment granules. When the skin becomes tanned on exposure to sunlight, the melanocytes do not increase in number, they only became more active. Not only do melanocytes produce a tan, they are also responsible for the form of cancer called melanoma. Melanoma is caused by UV radiation damage to melanocytes. Repeated exposure to UV can cause cancerous mutations [3].

**Types of Skin**

It is always beneficial to know which kind of skin you possess, as it can help in right care of skin and in reducing skin problems and avoiding diseases.

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There are mainly 5 types of skin:

1. **Normal skin**: It is soft, smooth, velvety and evenly textured skin with no flaky dead cells and no pores visible. Proper distribution of oil and moisture is there that makes it a balanced skin i.e. not excessively dry and not excessively greasy. It is clear and free from blemishes.

2. **Dry skin**: Skin is said to be dry, when skin is dull, patchy, reddened and flaky especially around eyes. Dry skin may cause formation of fine lines on cheeks, under eyes and corners of mouth. These conditions happen when oil or sebaceous glands are not supplying good nourishment and lubrication to the skin. If proper care is not given to the skin then it may lead to initiation of wrinkles in early age.

3. **Oily or greasy skin**: This kind of skin is thick, dull in colour and shiny in appearance. Due to over secretions of oils or sebum through oil gland, makes skin pores open and skin becomes sticky, which attracts dirt and dust from the environment. Due to this tendency, dirt and dust particles blocks the skin pores which are already widely open in oily skin leads to problems like black head, white head, acne and other skin related problems.

4. **Combination skin**: Commonly seen skin texture which is the combination of two kind of skin i.e. some of the skin area is dry and some of the area is oily. Usually it follows the pattern of “T”. The greasy part is usually the portion which is vertical to nose crossing nose (nose, mouth and chin) and horizontal on-fore head and hence referred to as “T-Zone”. The area left i.e. cheeks is comparatively dry.

5. **Sensitive skin**: This kind of skin is very sensitive to any change in environmental conditions or any kind allergies, which may be caused due to procedures like bleaching, makeup’s and other external applications.

   How to know that which type of skin you possess? It is a very simple method to know that what kind of skin you possess by following procedure mentioned below:

   Whenever you wake up in morning, wipe your face with dry tissue soon after leaving your bed. If you find oil on that tissue, you possess oily or greasy skin. If you find grease on the center panel then you possess combination skin. If there is no grease at all then you either have dry or normal skin. Now to check whether your skin is dry or normal, just wash your face with non-greasy soap and water. If you are left with the feeling of stretchiness and tightness on skin then you possess dry skin otherwise you have normal skin. If in daily routine you easily get skin allergies, rashes, itching and boils then your skin is sensitive.

### THE ULTRA-VIOLET RANGE

1. **UV-A**: Also called as long wave UV radiation, has wavelengths ranging from 320-400nm with a broad peak at 340nm. This range is believed to be responsible for the direct tanning of skin without a preliminary inflammation, possibly due to the photo oxidation of leuco form of melanin present in upper layer of skin; however it is weak in producing erythema.

2. **UV-B**: Also called as sunburn radiation or middle UV radiation, has wavelength ranging from 290-320nm with a peak of effectiveness around 297.6nm. This is the erythemogenic range of UV responsible for producing sunburn as well as irritating reactions which lead to the formation of melanin and development of tan.

3. **UV-C**: Also called as short wave UV radiation or the germicidal radiation, has wavelength ranging from 200-290nm. Although it is damaging to tissues, it is largely filtered from sunlight by ozone in the atmosphere. It can however be emitted by artificial UV sources. Though it does not stimulate tanning, but it may cause erythema.

The A, B and C bands of UV radiation emit different amounts of energy and produce an erythemal reaction at different time intervals after exposure.

### ENERGY

About 20-50 joules/cm² of UV-A radiation are required to produce minimally perceptible erythema compared with only 20-50mJ/cm² of UV-B energy and 5-20mJ/cm² of UV-C energy.

### TIME

In case of UV-A energy, erythema of the skin produced as a result of exposure to this radiation attains its maximum intensity at about 72 hours after exposure, while in the case of UV-B radiation the erythematic reaction reaches its maximum intensity within 6-24 hours after exposure.

### BENEFICIAL EFFECTS OF SUNLIGHT

Moderate exposure of the human body to sunlight, results psychologically and physiologically in a general sense of fitness, peace of mind and general well being. Various beneficial effects can be enumerated as below:

1. Increase in blood circulation.
2. Increases formation of haemoglobin.
3. Reduces the blood pressure.
4. It is also helpful in the prevention and treatment of rickets through activation of 7-dehydrocholesterol present in epidermis and secondly through vitamin D which enhances calcium absorption from intestine.
5. Treatment of skin diseases like psoriasis.
6. Reduces the susceptibility of individuals to various infections.
7. It produces melanin and causes thickening of skin, which plays an essential part in formation of body’s natural protective mechanism against sunburn.

### ADVERSE EFFECTS OF SUNLIGHT

Solar radiation can have both short term and long term adverse effects. UV-radiation, especially UVB (called burning Ray), produces dilatation of the blood vessels in the skin and, after prolonged exposure, an inflammation (erythema). Depending on the UV dose the skin melanocytes begin to produce melanin, a protein responsible for pigmentation. UVA (called aging Ray) produces less erythema and pigmentation than UVB but damages the skin by penetrating deeply into the dermis able of producing premature aging, wrinkles, and tumours.

1. **Sunburn**: The short term effect on skin, is a temporary damage of the epidermis, manifesting the known symptoms of sunburn. The symptoms of sunburn are direct result of damage or destruction of cells in prickle cell layer of skin, possibly through denaturing of its protein constituents. The damaged cells release histamine like substances which are responsible for the dilation of blood vessels and erythema. Additionally they are also responsible for oedema i.e. swelling of skin. It is a popular term applied to the marked erythema and pain that commonly follows injudicious sun exposure. Sunburn is a delayed ultraviolet B-induced erythema caused by an increase in blood flow to the affected skin that begins about 4 hours and peaks between 8-24 hours following exposure.

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Other effects accompanied in range of severity are from slight erythema to painful burns and blistering. According to Luckiesh the following definitions...
of four degrees of sunburn are mentioned:

- **Minimal Perceptive Erythema** - A slight but discernible red or pink coloration of skin, produced in 20 minutes.
- **Vivid Erythema** - A bright red coloration of the skin, not accompanied by any pain, produced in 50 minutes.
- **Painful Burn** - Characterized by both vivid erythema and pain ranging from mild to intense, produced in 100 minutes.
- **Blistering Burn** - Characterized by an extremely high level of pain accompanied by vivid erythema and possibly systematic symptoms with blistering and peeling, produced in 200 minutes[1].

### 2. Chronic Exposure

Chronic exposure to sun light, entails more serious hazards such as the development of skin cancer. It may also produce degenerative changes in the connective tissues and results in so called premature aging of the skin which is evidenced by the thickening of skin, loss of natural elasticity and appearance of wrinkles, all of which are due to loss of skin water binding capacity.

Excessive exposure to solar radiation can also aggravate or be the direct cause of some skin disease, ranging from transient dermatitis to skin cancer. A higher incidence of skin cancer would be expected to occur in regions with sunlight rich in shorter UV rays. Malignant growth occurs mainly in those regions of the body that receive the greatest amount of light such as the neck, head, arms and hands. It is also known that fair skinned people are far more susceptible to skin cancer than people with deeper pigmentation[1,7-10].

### SUNSCREENS

Sunscreens are the formulations which contain chemicals that provide protection against the harmful effects of UV radiation. Additionally they also contain other ingredients such as preservatives, moisturisers and fragrance. There are two types of chemicals in sunscreen:

- **Chemical filters**, which absorb UV radiation before it can damage the skin.
- **Physical filters**, which contain micro-fine particles that sit on the surface of the skin and act as a physical barrier.

Sunscreen can contain either chemical or physical filters, or may contain both. Chemicals in sunscreen are tested and approved as being safe, and there is no scientific evidence of health side effects from sunscreen. Regular use of an effective sunscreen is the single most important step to maintain healthy, youthful-looking skin. Mainly, it is the effect of ultraviolet light from the sun that causes most of the visible effects of ‘aging’ skin [11-13].

### CLASSIFICATION OF SUNSCREEN

Sunscreen can be classified on following two basis:

1. On the basis of active ingredient.
2. On the basis of application

#### 1. CLASSIFICATION ON THE BASIS OF ACTIVE INGREDIENT

They can be classified broadly into three categories:

- **Chemical (organic) sunscreens**
- **Physical (inorganic)sunscreens**
- **Natural sunscreens**

**Chemical Sunscreens** These act primarily by binding to skin protein and absorbing ultraviolet B (UVB) photons (280–320 nm) and most are based on para-aminobenzoic acid (or its derivatives), cinnamates, various salicylates and benzophenones, dibenzoylmethanes, anthraline derivatives, octocrylene and homosalate. Avobenzone is a benzophenone derivative with excellent ultraviolet A (UVA) protection [5, 6].

**Physical Sunscreens** Also called as sun blocks act as barriers, which reflect or scatter radiation. Direct physical blockers include metal containing compounds such as iron, zinc, titanium, and bismuth. Zinc oxide and titanium dioxide are highly reflective white powders, but submicron zinc oxide or titanium dioxide powder particles transmit visible light while retaining their UV blocking properties, thus rendering the sun block invisible on the skin [5, 6].

**Natural Sunscreens** There is increasing evidence that various natural compounds offer some UV protection. However, natural compounds do not scatter or absorb UV radiation but rather protect the skin cells from being damaged by UV radiation, mostly through antioxidant effects. Evidence of effective photoprotection has been accumulating with green and black tea. Various other agents used in natural sunscreens are curcumin, carrot, tomatoes, grapes, gingko biloba etc [5, 6, 14,15].

#### 2. CLASSIFICATION ON THE BASIS OF APPLICATION

They can be broadly classified as:

- **Sunburn preventive agents**
- **Suntanning agents**
- **Opaque sunblock agents**

**SUNBURN PREVENTIVE AGENTS**

These are defined as the sunscreens which absorbs 95% or more of UV radiations within the wavelengths 290-320 nm [1].

**SUN TANNING AGENTS**

These are defined as sunscreens which absorb atleast 85% of UV radiations within wavelength range from 290-320nm but which transmits UV light at wavelengths longer than 320nm and produce a light transient tan. These agents produce some erythema but without pain [1].

**OPAQUE SUNBLOCK AGENTS**

These provide maximum protection in the form of a physical barrier. Titanium dioxide and zinc oxide are the most frequently used agents in this group. Titanium dioxide reflects and scatters practically all radiation in the UV Visible range (290-777nm), thereby preventing or minimizing both sunburn and suntan [1].

### SELECTION OF SUNSCREEN

Following factors should be considered while selecting a sunscreen

- **Sun Protection Factor**: The SPF protects against UVB radiation. A sunscreen is given an SPF number (of between 4 and 30+) after strict laboratory testing. The higher the SPF number, the more protection the sunscreen provides against sunburn. A sunscreen with a SPF of 15 provides >93% protection against UVB. Protection against UVA is increased to 97% with SPF of 30+. The difference between a SPF 15 and a SPF 30 sunscreen may not have a noticeable difference in actual use as the effectiveness of a sunscreen has more to do with how much of it is applied, how often it is applied, whether the person is sweating heavily or being exposed to water.[16]

- **Children**: Sun exposure in the first 20 years of life is a strong determinant for the risk of skin cancer. Therefore sun protection throughout childhood and teenage years is probably crucial to preventing such carcinogenesis. Direct sun exposure should probably be minimized in children, and if they must spend periods of time outside during the day, physical blockers such as clothing
should be used; failing that, sunscreens, sprays and gels should be used with caution in young children as they can irritate the skin and exacerbate atopic dermatitis. Sunscreens are not recommended for use in children less than 6-12 months of age in order to discourage unnecessary sun exposure. However, there is no strong reason to suggest that sunscreens are harmful in this age group [17, 18].

•Substancy: It is the ability of a sunscreen to resist its removal by physical means such as sweating or contact with water. If the SPF of a sunscreen stays unchanged after 40 minutes of contact with water, it is said to be water resistant, whereas if it stays unchanged for 80 minutes or more, it is said to be waterproof. Thus a person staying outside in a pool for six hours may wish to reapply a waterproof sunscreen at least four times to ensure that the SPF remains unchanged. Some manufacturers state the actual time their product remains waterproof, and products which are waterproof for six hours or more should be used if prolonged exposure to water or prolonged sweating is anticipated [17].

•Allergic potential: The prevalence of allergic reactions to sunscreens is low and most reactions reported by patients are of the irritant type. PABA and its derivatives, benzophene and fragrances are among the most allergenic ingredients in sunscreens, explaining why many commercial products no longer contain PABA. Physical sunscreen agents do not cause allergic contact dermatitis [17].

•Photodegradation: Certain sunscreen agents like avobenzone (Parsole 1789) have been shown to isomerize and lose part of their sun protection properties when exposed to light, whereas others like the newer agent Mexoryl-SX are especially photostable. In vitro studies have shown that certain sunscreen formulations can lose more than half their SPF value after one hour of artificial light exposure, suggesting that photodegradation is an important factor to consider when evaluating sunscreens. In vivo studies are needed comparing the photostability of sunscreens to both UVA and UVB [17, 19, 20].

SUNSCREEN AGENTS

Sunscreens should either scatter the incident light effectively or they should absorb the erythematic portion of sun’s radiant energy. The properties necessary in a sunscreen are:

1. It must be effective in absorbing erythemogenic radiation in the 290-320 nm range without breakdown which would reduce its efficiency or give rise to toxic or irritant compounds.
2. It must allow full transmission in the 300-400 nm range to permit the maximum tanning effect.
3. It must be non-volatile and resistant to water and perspiration.
4. It must possess suitable solubility characteristics to allow the formulation of suitable cosmetic vehicle to accommodate the requisite amount of sunscreening.
5. It must be non-odorous or at least sufficiently mild to be acceptable to the user and be satisfactory in other physical characteristics such as stickiness etc.
6. It must be non-toxic, non-irritant and non-sensitizing.
7. It must be capable of retaining its protective capacity for several hours.
8. It must be stable under conditions of use.
9. It must not stain clothing [1].

SKIN TYPES AND RECOMMENDATION FOR CHOICE OF SUNSCREENS

The extent to which a sunscreen product protects from sunburn and other harmful effects of exposure to sunlight varies with the individual skin type. A classification system for sunscreening products according to Federal Register,1978,43(166),38206 comprises five product category designations to meet requirements of consumers with different types of skin [21].

Individuals can be classified into six groups according to skin type and tanning history

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<th>SKIN TYPE</th>
<th>SPF</th>
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<td>I</td>
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<td>II</td>
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The product category designations recommended to consumers in selecting the type of sunscreen product providing various SPF’s are as follows:

PCD1: Minimal sun protection product
Provides an SPF value of 2 to under 4 and offers the least protection but permits suntanning.

PCD 2: Moderate sun protection product
Provides an SPF value of 4 to under 6 and offers moderate protection from sunburning, but permits some suntanning.

PCD 3: Extra sun protection product
Provides an SPF value of 6 to under 8 and offers extra protection from sunburning, permitting little or no suntanning.

PCD 4: Maximal sun protection product
Provides an SPF value of 8 to under 15 and offers maximal protection from sunburning, permitting little or no suntanning.

PCD 5: Ultra Sun Protection Product
Provides an SPF of 15 or above and offers greatest protection from sunburning, permitting no suntanning.

For the guidance of consumers the OTC panel has recommended that the following labelling statements are prominently placed on the principal display panels of appropriate products [1].

1. For minimal sun protection products SPF 2
   ‘stay in the sun twice as long as before without sunburning’.

2. For moderate sun protection products SPF 4
   ‘stay in the sun 4 times as long as before without sunburning’.

3. For medium sun protection products SPF 6
   ‘Stay in the sun 6 times as long as before without sunburning’.

4. For maximum sun protection products SPF 8
   ‘stay in sun 8 times as long as before without sunburning’.

5. For ultra sun protection products SPF 15
   ‘stay in the sun 15 minutes as long as before without sunburning’.

HOW TO APPLY SUNSCREENS

When the objective to cover the exposed skin surface is remembered then the sunscreen does become more intuitively useful. The skin needs
to be well covered but only lightly rubbed in. Especially sunscreens containing inorganic UV absorbers, reflectors, and scatters like titanium dioxide and zinc oxide, should not be rubbed too hard as they work best on the surface of the skin. If sunscreen is not spread enough when applied over the skin then the person will not be protected according to the label claimed SPF. Sunscreens are considered therapeutics rather than cosmetics and thus fall under strict regulatory requirements regarding their safety. Nevertheless some people may react adversely, with irritation or allergy. It is therefore a good idea, especially when trying a sunscreen that you have not used before, to apply a little to a small area of skin and leaving it there for as long as you can. While this may not be a sufficient self test to completely assure of an unproblematic usage, it will at least reveal whether there is any immediate irritancy. Following points should be remembered while using the sunscreen to get the maximum protection

• Broad-spectrum sunscreen of at least SPF 15 should be used and made up of a benzophenone chemical absorber plus a physical blocker (titanium dioxide or zinc oxide).
• A product that complies with the current Australian and New Zealand Standard for Sunscreens (AS/NZS2604:1998), or equivalent in other countries should be used.
• Sunscreen should be applied liberally to all sun-exposed areas so that it forms a film when initially applied. Most people use sunscreens improperly by not applying enough.
• It takes 20–30 minutes for sunscreen to be absorbed by the skin and it can be rubbed off very easily, so it should be applied at least half an hour before going out in the sun and should be reapplied after every half an hour.
• Sunscreens should be applied every 2 hours if staying out in the sun for more than an hour during the day.
• It should be reapplied immediately after swimming, excessive sweating, or if rubbed off by clothing or towelling. This should be the case even if the product claims to be “water resistant”.
• Insect repellents reduce the sunscreen’s SPF so when using together, use a sunscreen with a higher SPF and re-apply more often.
• Alcohol-based lotions, sprays or gels are better for oily or hairy skin. Creams are suitable for dry skin, and milky lotions are the easiest to apply [16].

APPLICATION OF SUNSCREEN

The ideal sunscreen should have an ideal SPF rating, be well tolerated, cosmetically pleasant, non-toxic, equally effective against UV-A and UV-B, photo stable, water-resistant and inexpensive. Unfortunately no single such sunscreen currently exists. Sunscreens should be applied 20 to 30 minutes before sun exposure so the product has a chance to bond with a skin. Products containing PABA and PABA-like derivatives however may be need to be applied up to two hours in advance to sun exposure in order to achieve their maximal effect. Contrary to the common advice that sunscreen should be reapplied every 2-3 hours, research has shown that the best protection is achieved by application 15-30 minutes before exposure, followed by one reaplication 15-30 minutes after the sun exposure begins. Further application is only necessary after activities such as swimming, sweating and rubbing.

To cover the average 1.73 m² adult, approximately 35ml of sunscreen is required. The teaspoon rule of applying sunscreen is as follows: apply slightly more than half teaspoon (3 ml) to each arm, to the face and the neck, apply slightly more than a tea spoon (6 ml). Using an adequate amount of sunscreen 2mg/cm² provides greater sun protection than using an inadequate amount of sunscreen with a higher SPF rating. Patients should select broad spectrum sunscreens that contain agents that effectively block both UVB and UVA rays with an SPF of 30 or greater. A sunscreen with a SPF of 15 filters out 97%. SPF applies only for UVB rays. The protection provided against UVA rays in chemical sunscreens is about 10% of UVB rating [22, 23].

SUNSCREEN VEHICLE

To select a suitable vehicle is necessary for obtaining an efficient sunscreen with increased efficacy and aesthetics. Ingredients, such as solvents and emollients, can produce a significant effect on the strength of UV-absorbance by the active ingredients and at which wavelengths they absorb. Film formers and emulsifiers determine the nature of the film that forms on the skin surface. Products with a higher SPF need a formula that will form a uniform and thick sunscreen film with minimum interaction between inert ingredients and the actives. Durability and water resistance are two important parameters which are vehicle dependent. Lastly, product aesthetics play a large role in patient compliance with specific sunscreen recommendations.

The most popular sunscreen vehicles are lotions and creams. Two-phase oil-in-water or water-in-oil emulsion systems allow for the widest variety in formulation. Most sunscreen ingredients are lipid soluble and are incorporated into the oil phase of the emulsion. Products with higher SPF may contain up to 20-40% sunscreen oils, accounting for the occlusive greasy feel of many of these products. Dry lotions, often marketed as sport lotions, represent the formulator’s attempt to provide a less oily product. Newer “ultrasheer” products further refine these qualities with the use of silica as a major vehicular component. Gels, sticks, and aerosols are the other vehicles for organic sunscreen ingredients. Water- or alcohol-based gels provide less greasy aesthetics, but they rely on the more limited number of water-soluble sunscreen ingredients and are less substantive with a greater potential for irritation. Sticks readily incorporate lipid-soluble sunscreens thickened with waxes and petrolatum and are heavier on application, but are useful for areas, such as the lips, the nose, or around the eyes. Aerosols although are convenient to use but when applied do not form a uniform film.

Sunscreens have been incorporated into a broad range of consumer products, including daily-use cosmetics. The FDA monograph now distinguishes between beach and nonbeach products.

Daily protection is facilitated for a large segment of the population. Sunscreens/moisturizers are available throughout the year, as opposed to seasonal beach products. Moisturizers containing sunscreen agents are mostly oil-in-water emulsions. To decrease the oil phase and to increase the cosmetic elegance water-soluble sunscreen ingredients are preferred. Foundation makeup with no sunscreen agent provides almost an SPF of 3 or 4 by its pigment content. By raising the level of pigments, including inorganic sunscreen particulates, titanium dioxide and zinc oxide, product with higher SPF can be obtained with or without using organic chemical sunscreens. Makeup with sunscreen has intrinsic full-spectrum UV-A protection based on opacity. Lipsticks contain chemical sunscreens to provide enhanced SPF protection.

Sunscreen agents when used with DEET (N,N-diethyl-m-toluamide)—containing insect repellents, results in decrease in sunscreen efficacy and an increase in DEET absorption. Combination products such as these should be used cautiously [24].

Photostability and Toxicity

Photostability refers to the ability of a molecule to remain intact with irradiation. This issue has been raised specifically with avobenzone, with photolysis demonstrated, especially in vitro systems that simultaneously irradiate and measure transmittance in situ. This effect may degrade other sunscreens in a formulation. This change has also been observed with octyl methoxycinnamate and octyl dimethyl PABA, while oxybenzone was shown to be relatively stable. Higher SPF sunscreen products have led to the use of multiple individual sunscreen agents used in combinations at maximum concentrations that may interact. The photostability of the molecules also depends on the solvent or the vehicle used. Certain ingredients may have a stabilizing effect on others; octocrylene has been shown to photostabilize avobenzone.

Subjective irritation associated with burning or stinging without objective erythema is the most common sensitivity complaint from sunscreens. This irritation is most frequently observed in the eye area. Fragrances, preservatives, and other excipients account for many of the allergic reactions that occur with sunscreens. Virtually all sunscreen ingredients reported to cause contact allergy might be phototoxic. Sunscreens containing inorganic particles (titanium dioxide and zinc oxide) provide a good option for individuals...
with sensitive skin because these ingredients are not associated with irritation or sensitization [24].

EVALUATION

1. SUN PROTECTION FACTOR

SPF stands for Sun Protection Factor and is the system used worldwide to determine how much protection a sunscreen provides, applied to the skin at a thickness of 2 mg/cm². The test works out how much UV radiation (mostly UVB) it takes to cause a barely detectable sunburn on a given person with and without sunscreen applied.

For example, if it takes 10 minutes to burn without a sunscreen and 100 minutes to burn with a sunscreen, then the SPF of that sunscreen is 10 (100/10). A sunscreen with a SPF of 15 provides >93% protection against UVB. Protection against UVB is increased to 97% with SPF of 30+. The difference between a SPF 15 and a SPF 30 sunscreen may not have a noticeable difference in actual use as the effectiveness of a sunscreen has more to do with how much of it is applied, how often it is applied, whether the person is sweating heavily or being exposed to water. Hence a sunscreen with SPF 15+ should provide adequate protection as long as it is being used correctly [1, 3, 17, 25].

SUBSTRATE METHOD

Substrate methods have been widely used for the determination of SPF in vitro. The ideal substrate for in vitro SPF needs to be fairly transparent to the ultraviolet and simulate the porosity and texture of human skin, the in vivo substrate. Suitable in vitro substrates range from human epidermis and mice epidermis to sausage casings and natural lamb condoms. The three common substrates used are Transpore Tape, Vitro-Skin, and Polyvinyl Chloride Film.

Transpore tape It is a surgical tape manufactured by the 3M Company. The tape is readily available and inexpensive. The adhesive side makes it easy to apply to a quartz microscope slide for a rigid working surface. Although the tape is discarded for each prepared sample, the quartz slides can be washed and used again. The use of this substrate was first evaluated by Diffey and Robson [26]. It was selected for its uneven topography that distributes the sunscreen in a way similar to human skin. The method gives the reproducible results. The main advantages of the Transpore tape are its low cost, ready availability, and ease of use. There are a few disadvantages that need consideration when using Transpore tape: (a) the tape will not absorb formulations that use alcohol or oil as a vehicle; (b) pore size can vary at the beginning and end of each roll therefore, it is recommended to discard the first two feet at the start and end of each roll.

Diffey and Robson [26]

The method is based on critical wavelength and use thin-film substrate spectrophotometry. The definition of the critical wavelength (λc) is the wavelength at which the integral of the spectral absorbance curve reaches 90% of the integral from 290 to 400 nm.

\[
\int_{\lambda} A(\lambda) d\lambda = 0.9 \int_{\lambda} A(\lambda) d\lambda
\]

where \(A =\) absorption; \(d\lambda =\) wavelength interval used in the summation.

Vitro-Skin It is a registered trademark of IMS Inc., is a synthetic skin substitute that has been widely used for in vitro analysis of sunscreens. Once hydrated, Vitro-Skin has a texture very similar to human epidermis. In addition, the hydrated material seems to help sunscreen emulsions break down in much the same way as human skin. Published data by the producer of Vitro-Skin indicates that the substrate gives excellent correlation with in vivo SPF measurements. The primary advantages of Vitro-Skin are its topographical similarity to human skin and the ability to break down emulsions. The apparent disadvantages are: (a) a relatively high cost per sample—approximately $1.50 per test compared to pennies for other methods; (b) an overall low UV transmittance, especially at low wavelengths; (c) the need to hydrate the substrate starting the day before testing; (d) a relative short lifetime of the hydrated Vitro-Skin.

Polyvinylchloride Film Polyvinyl chloride or polyvinylidene chloride film, available under the commercial tradename SaranWrap®, is a highly transmissive material in the UV-Visible portion of the spectrum. While the film does not have the texture of human skin, it is very easy to form uniform dispersions of sunscreen products on the material. Commercially available polyvinyl/vinylidene chloride films are also extremely uniform in their material properties from roll to roll, and throughout each individual roll.

1. IN VIVO COLIPA METHOD

The test products should be applied in the amount of 2 mg/cm² on the upper back of the volunteer 15 min prior irradiation. UV radiation source with continuous emission spectrum 290–400 nm should be used as the source of radiation. The UV source should irradiate an area of 5·6 cm in six points (diameter 1 cm), in a series of doses increasing geometrically (factor 1.25). Radiometer should be used for the measurement and automatic delivery of radiation doses. The visual assessment of skin reactions should be performed 16–24 h after UV exposure by a single trained evaluator. For each subject, the Minimal Erythema Doses on unprotected skin and on skin protected by the test products should be recorded. The SPF for the product should be calculated as the arithmetic mean of all individual SPF values obtained from all subjects in the test. The selection of volunteers and the test method should be carried out in accordance with the ethical principles as set out in the Declaration of Helsinki and International Ethical Guidelines for Biomedical Research Involving Human Subjects [27-29].

2. IN VITRO METHOD

The method is based on the measurement of attenuation of UVB intensity on a defined layer of a sunscreen product. The measuring system includes UVA / UVB source, a sheet of Mikelanta covering paper for the application of a defined layer of the tested product and radiometer for UVB radiation intensity measurement. The test samples should be applied on the Mikelanta paper in the amount of 2 mg/cm², distributed over the surface by rubbing the surface with an ungloved finger for 20–30 strokes and let to dry for at least 20 min. Then the rest of the product from the surface of the paper was removed by a small plastic spatula. Twenty spot measurements of the attenuated UVB radiation intensity were taken from each paper strip and an average attenuation value was calculated. The result of attenuation of UVB intensity should be transformed to real SPF value using a calibration curve. The calibration curve should be based on comparison of an extensive number of measurements performed using both in vivo and in vitro physical methods in the past years. On the y-axis, the ratio of UV intensity attenuated by Mikelanta paper without sunscreen product and UV intensity attenuated by Mikelanta paper with applied sunscreen product should be displayed. On the x-axis, the corresponding SPF values obtained by measurement in vivo are exhibited. When for a distinct product the ratio should be calculated on the basis of in vitro measurements, the expected SPF can be identified on the x-axis [27].

3. IN VITRO METHOD (SONING)

The method is based on the measurement of attenuation of UVB intensity on a defined layer of a sunscreen product. The measuring system includes a UVB source, a sheet of tracing paper for the application of a defined layer of the tested product, and an electronic UVB intensity meter. The test samples should be applied on the tracing paper in the amount of 2 mg/cm², distributed over the surface by rubbing the surface with an ungloved finger for 20–30 strokes and let to dry for at least 20 min. Then the rest of the product from the surface of the paper should be removed by a small plastic spatula. Twenty spot measurements of the attenuated UVB radiation intensity should be taken from each paper strip and an average attenuation value should be...
Anti-oxidant / anti-radical activity should be measured by monitoring the decrease in absorbance at 517 nm of coloured DPPH (1, 1-diphenyl-2-picrylhydrazyl) brought about by the sample. A stock solution of DPHH 0.1 mM should be prepared by dissolving 3.94 mg in 100 ml of methanol: water (50:50). The stock solutions of the gel formulation 1 mg/ml should be prepared using methanol:water (50:50) as a solvent. 0.1 ml of stock solution of should be pipetted out and diluted to 100 ml to get 10 µg/ml. Subsequent dilutions of stock solutions of gel should be done to get the suitable concentration of the solutions. 1 ml of DPPH solution should be added to 3 ml of hydroalcoholic solution [(Methanol: water (50:50)] and initial absorbance recorded at 517 nm after 30 min. Decrease in absorbance in the presence of sample solutions at different concentrations should also be noted after 30 min. The percent inhibition / percentage DPHH scavenging activity should be calculated from following formula

\[
\text{DPPH Scavenging} = \frac{\text{Absorbance of Control} - \text{Absorbance of Test Sample}}{\text{Absorbance of control}} \times 100
\]

IC should be calculated from % DPHH scavenging activity. Ascorbic acid should be used as standard [29].

6. SKIN IRRITATION STUDIES

The scores for erythema and edema should be totaled for intact and abraded skin for all rabbits at 24 and 72 hours. The primary irritation index (PII) should be calculated based on the sum of the scored reactions divided by 24 (2 scoring intervals multiplied by 2 test parameters multiplied by 6 rabbits). The developed formulation should show no erythema or edema on the intact and abraded rabbit skin.[30].

7. MEASUREMENT OF BROAD SPECTRUM TRANSMISSION

There are 3 alternative test methods for determining the broad spectrum transmission by a sunscreen. The percentage transmittance of a solution of the product (Method 1), a thin film of the product in a cell (Method 2) or a thin film of the product on a flat plate (Method 3) is determined between 320 nm and 360 nm equivalent to an 8 µm (Methods 1 and 2) or 20 µm (Method 3) layer on the skin. The method to be used will depend on the composition of the product.

Performance Requirements

A broad-spectrum claim cannot be made for a product with an SPF less than 4. If tested in accordance with the (solution) Method 1 or thin (wet) film Method 2, an 8 µm layer of the product shall not transmit more than 10% of radiation at any wavelength from 320 nm to 360 nm inclusive; or if tested in accordance with the plate (dry film) Method 3, the ultraviolet transmittance of a 20 µm layer of the product in the wavelength range 320–360 nm shall be not more than 1%.

METHOD 1—SOLUTION METHOD

This method is used for a product that dissolves completely in a solvent mixture consisting of Dichloromethane 12.5: Cyclohexane 37.5 :Isopropanol 50.0. A lidded 10 mm quartz cell is filled with a dilution of the sample of - 0.8 mg/mL. Transmission of the sample between 320 nm and 360 nm is determined against the solvent blank.

METHOD 2—THIN FILM METHOD

This method shall be used for a product that is opaque by reflection rather than absorption or which does not dissolve completely in the solvent of Method 1. A quartz cell with suitable lid, constructed to provide an 8 um layer of sunscreen product for testing is used. The cell is filled with the sunscreen product and determines the transmission of the product from 320 nm to 360 nm inclusive.

METHOD 3—PLATE METHOD

This method of sample preparation is suitable for testing all sunscreen products regardless of the solvents used and whether the sunscreen includes suspended solids. Quartz plates for sample preparation, of a size appropriate to the instrument are used. A Plastic film, nominally 20 um thick, is used as a template and the product is applied in a controlled thickness to a quartz plate, by ladling the film level with a razor blade. Transmission of the product from 320 nm to 360 nm is determined [15].

9. MEASUREMENT OF PERCUTANEOUS ABSORPTION

There are several methods to measure in-vivo absorption. Like all in-vivo methods, they have the advantage of being more true to a real-life situation. Negative aspects are that they are usually more expensive and that people or animals have to be exposed to the compounds. In-vitro methods are more easily controlled but cannot account for processes in the body [31]. Table 4 summarizes the advantages and disadvantages.

Table 4 Advantages and disadvantages for in-vivo and in-vitro methods.

<table>
<thead>
<tr>
<th>Method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-vivo</td>
<td>1. Biological response</td>
<td>1. Exposure to humans/animals</td>
</tr>
<tr>
<td></td>
<td>1. Less expensive</td>
<td>2. Expensive</td>
</tr>
<tr>
<td></td>
<td>Less risk for humans/animals</td>
<td>1. No biological endpoint</td>
</tr>
<tr>
<td></td>
<td>2. Reproducible</td>
<td></td>
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</tbody>
</table>

In-vivo methods for absorption measurements [32]

1. Radioactivity in blood or excreta

The radioactivity in blood or excreta can be measured after topical application of a labelled compound. It is common to use carbon14 or tritium. This method does not take into consideration that the compound can be metabolized.
CONCLUSION

Sunscreens are very useful category of cosmetic agents but the indiscriminate use of these agents can result in its harmful effect and complications. So the sunscreen application should be decided on the basis of its SPF and the sensitivity and type of the skin of the person. There are various approaches for the evaluation of sunscreen. The method of application of sunscreen should be efficient enough to minimize the undesirable effects and maximize the beneficial effects.

REFERENCES


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