UV AND SUNSCREEN
RESEARCH UPDATE

P&G beauty

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DEFINING ISSUES

Advances in Science

Tanning Is Last Century

The Parisian fashion designer Coco Chanel had no idea that she was unleashing a cascade of biological events when she charmed and shocked her fans by sporting a tan after a holiday on the French Riviera.

Ever since Chanel helped launch the sunbathing fad in the 1920s, dermatologists have been trying to lure their patients away from the toxic allure of tanning. Before they realized the risks, women's magazine editors had advised generations of readers on ways to acclimatize skin to UV and build up a tan. Companies made sunlamps in the '40s for sunless tanning. People bought reflectors and baby oil in the '50s to encourage even coloring. And when the earth children of the '60s absorbed sun unfettered by clothing, UV protection was not yet marketed.

When efficacious sunscreen products became available in the 1970s, the fairest Fitzpatrick skin types (I-III)[1] gave a collective sigh of relief. As the impact of sun damage became clearer, and product design improved, the total fascination with deep, dark tans slowly started to fade.

Increasingly pleasant-to-use sunscreen formulations have made it possible to play a round of golf or sit on the beach without a telltale appearance of white zinc blotches or greasiness. The earliest sunscreen products were formulated primarily to ward off sunburn by blocking short wavelengths, e.g., UVB, and did not deliver broad-spectrum protection from UV. More than three decades later, blocking the breadth of UV, i.e., so-called UVB and UVA, is still the greatest challenge of sunscreen protection.

The Burning Truth

Today, 70 percent of Americans are aware that daily sun exposure causes skin damage. However, in the heyday of the tan, information about how sun exposure caused skin problems was scarce. For decades, the average person was unaware that her "healthy glow" was actually sun damage. With the introduction of tanning beds in the 1970s, people had an easier way to tan, but were exposed to greater levels of UVA than from sunlight.[2] Today, 22 million Americans tan in more than 24,000 tanning salons in the United States and continuously put themselves at risk for premature aging and skin damage that may lead to skin cancer.[3]

In 1978, the U.S. Food and Drug Administration (FDA) concluded that sunscreens may help prevent skin cancer. Such findings have led professional organizations, such as the American Academy of Dermatology (AAD), to institute public education campaigns about the risks associated with tanning, whether solar or by artificial light.

Sunscreen use rose from 35 percent in 1986 to 53 percent in 1996.[4] This increase in usage as part of a "safe sun" strategy may be slowing the rising rate of non-melanoma skin cancer;[5, 6] nonetheless, the skin cancer incidence continues to increase. Most troubling is that the incidence rate for melanoma is growing faster than any other cancer. Although the exact mode of action has yet to be determined, there is agreement among health care professionals that reducing solar UV is needed to diminish the risk of skin damage.

Despite the fact that most people are now aware of the benefit of using sunscreen when sunbathing or engaging in outdoor activity for long periods of time, awareness does not always translate into taking the necessary precautions. Additionally, many people are unaware that the daily or incidental exposure they receive necessitates everyday application of a sunscreen product.[7]

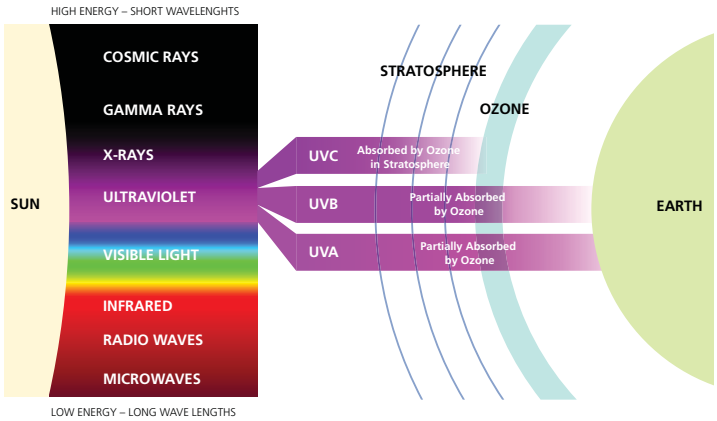
Sunscreen Protection Facts

- The dose-dependent aspect of sunscreen efficacy is not widely understood. In other words, the labeled SPF (Sun Protection Factor) is delivered when the product is applied at a dose of 2 mg/cm². Few know that insufficient application leaves skin vulnerable to exposure or lower than expected or labeled protection.
- The SPF number indicates how much longer one can stay out in the sun on a proportional basis in relationship to zero protection — 30 times longer when wearing SPF 30, 15 times longer wearing SPF 15. However, many assume that the UV filtration level also doubles along with the numbers. Actually, SPF 30 only blocks 3 percent more erythemally-weighted UV than SPF 15.
- Some sunscreen products labeled broad-spectrum protection lack broad UVA filtering capability, but many people are unaware of this discrepancy.

Lab Notes

Dissecting UV Rays

The shorter range of UVB rays (290-320 nanometers) that reach the earth cause the most readily recognized changes to the skin, such as erythema, pigmentation and skin cancer.[8] An estimated 95 percent of the UV



Invisible ultraviolet light is described as three wavelengths. UVC is absorbed by the ozone layer of Earth's atmosphere. UVB is partially absorbed by the ozone layer. UVA penetrates the atmosphere and reaches the earth.

rays that reach the earth are within the UVA spectrum from 320-400 nanometers. These rays are believed to penetrate deeply into the dermis.

While the solar UV spectrum is continuous, and not actually divided, it is a scientific convenience to describe the light as ranges. Specifically:

- Higher energy UVC light is 200-290 nanometers. It is dangerous, but almost completely absorbed by the ozone layer before reaching the earth (natural sun protection).
- The main erythema-producing UVB light range is 290-320 nanometers. These rays penetrate the atmosphere and cause skin-damaging sunburns and photoaging even on cloudy days. There is mounting evidence that exposure is a causal factor in skin carcinogenesis.
- The pervasive lower energy UVA light range is 320-400 nanometers. Research links exposure to skin aging and carcinogenesis. It remains difficult to define a meaningful endpoint to establish UVA protection levels in sunscreen products.

Biological Facts

Doing a Slow Burn

The degree of photodamage caused by UV depends partly on skin type. The etiology of skin cancer, non-melanoma and melanoma, is not fully known, but exposure to ultraviolet radiation is a recognized risk factor. This is especially true for those who have lightly pigmented skin, a large number of nevi and genetic predisposition.

Inflammation, a burning sensation and peeling (hyperproliferation) are obvious signs of short-term cell damage. The long-term consequences range from the cosmetic — wrinkles, roughness, laxity and mottled pigmentation — to the fatal — death from malignant melanoma.[9] It is not uncommon to see elderly individuals with the stark contrast of smooth skin where clothing has prevented UV exposure and a dramatically different, sun-ravaged complexion where UV exposure has been chronic.

It is not unusual for an 80-year-old to have the smooth, unblemished shoulders of a 30-something — proof that skin protected from solar UV ages more gracefully.

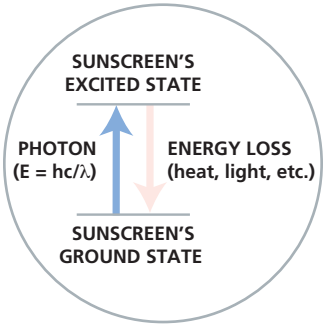
Skin has natural protection. The stratum corneum scatters radiation and melanin absorbs and reflects solar light. Antioxidants and repair enzymes become "active" in response to solar UV exposure. However, persistent exposure may overcome the skin's natural defenses. While light skin is usually more vulnerable, darker skin is not completely immune to sun damage.

Solar UV Exposure Poses a Year-round Risk

- **The damaging effects of UV exposure are cumulative.** Repeated exposure reduces the skin's ability to repair itself. Serious skin damage is done years before it becomes visible.
- **Just one day** of unprotected sun exposure:
  - Compromises the skin's immune system, such as the number of Langerhans cells.[10]
  - Increases sunburn cells indicating DNA damage that can lead to skin cancers and premature aging.
- **Visible evidence of UV damage develops hours after sun exposure.** It takes from two to 24 hours for surface skin damage to show up on skin.
- **Skin Types I, II and III (Fitzpatrick classification) are the most susceptible to erythema**, but all skin types are susceptible to UV damage and should be protected.[11]
- **Currently, between 2 and 3 million non-melanoma skin cancers and 132,000 melanoma skin cancers occur globally each year.** One in every three cancers diagnosed is a skin cancer and, according to Skin Cancer Foundation statistics, one in every five Americans will develop skin cancer in their lifetime.[12]

An Added Layer of Protection

Today, the goal of sun protection is to shield skin from solar UV radiation, protecting against both short-term and long-term harm to maintain or improve skin health. Whereas reducing sunburn is the first goal of sunscreen, it is known that protection against the breadth of solar UV is important as well. The sunscreen ingredients in products reduce the dose of solar UV to varying degrees. It is the synergy of the combined ingredients which delivers optimal skin protection.



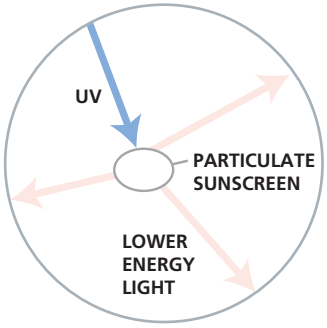
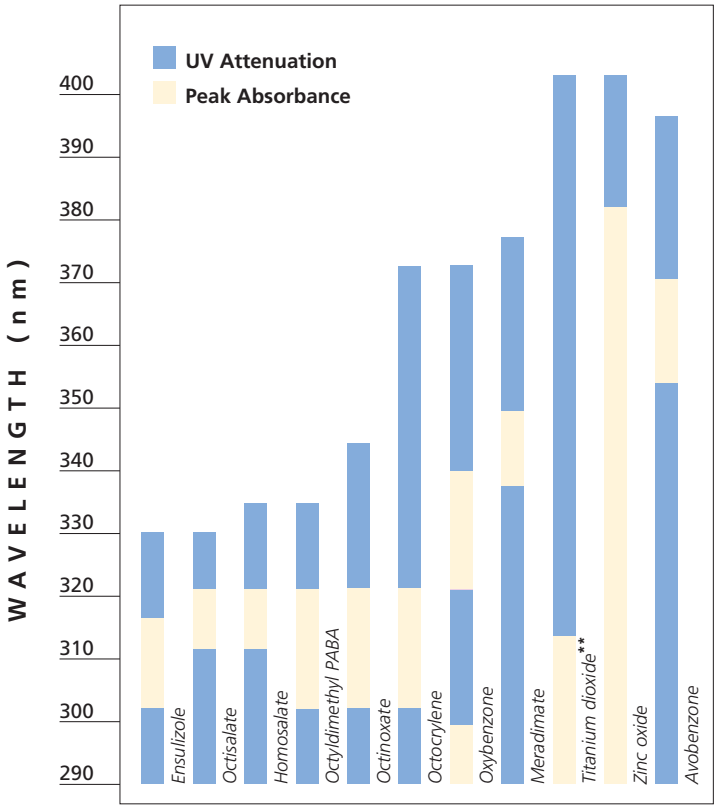


Diagram 1 (left): *UV absorption mechanism of sunscreens*
Diagram 2 (right): *UV scattering mechanism of sunscreens*

CHART 1: COMPARISON OF UV ATTENUATION* OF MOST WIDELY USED U.S. SUNSCREENS[13]



** The UV attenuation is based on substrate spectrophotometry determinations. Filters were prepared in a representative oil-in-water emulsion.*
*** Shape of the UV attenuation spectra varies with particle size.*

There are two categories of UV filters: organic and inorganic. The organic sunscreens are commonly referred to as "chemical." These agents protect against UV by absorbing the energy from UV rays (Diagram 1). The inorganic sunscreens, such as metal oxides or particulate UV filters, are often termed "physical" or "mineral." The metal oxides, namely titanium dioxide and zinc oxide, are insoluble particles which absorb and reflect UV (Diagram 2). The differences are primarily based on their solubility with organic UV filters existing in solution, and physical ones being suspended or insoluble. On the other hand, the inorganic sunscreens, zinc oxide and titanium dioxide, have excellent safety profiles since skin penetration is limited or negligible. Additionally, the photostability of metal oxides is largely independent of the vehicle and other ingredients.

The two categories of UV filters include a wide range of sunscreens that have an array of variables, such as mode of action, solubility and form (see Table 1, right). Beyond the obvious difference of physical form, sunscreens also absorb UV across a wide range of wavelengths. Each sunscreen absorbs UV across a

specific range and also a narrow area for its peak absorbance where its absorbance is most effective (see Chart 1, left). Due to the narrow absorption spectrum of a single ingredient, a combination of sunscreen actives is required to provide broad-spectrum UVA/UVB protection.

Application or Dose

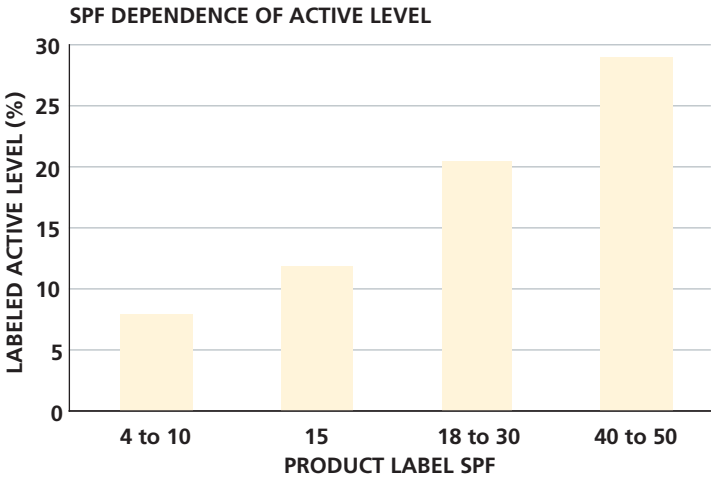
The SPF listed on the label is based on controlled clinical testing using 2 milligrams of lotion to cover one square centimeter of skin. The practical translation is that it takes approximately 0.5 grams of lotion for face and neck and 30 grams or more for an average body to have the full effective application. However, this application level often feels like too much since many sunscreen products are heavy, thick or greasy. Poorly formulated product is likely a primary reason sunscreen is under-applied.

Achieving a higher SPF requires that significantly more UV filters are added into the product, while achieving a slight increase in erythemally-weighted UV absorbance. Since the majority of sunscreens are oily liquids, this addition will cause a heavier skin feel. An SPF 15 product blocks 93.3% of burning UV rays, while an SPF 30 product blocks 96.7% of burning UV rays, or only about 3.4% more UV rays absorbed. Thus, both

TABLE 1: GLOBALLY USED SUNSCREEN INGREDIENTS AND THEIR PROPERTIES

Sunscreen Class	Sunscreen	Maximum Level in the U.S.	Mode of Action	Main Wavelengths Attenuated	Physical Form	Solubility	Comments
Cinnamates	Octinoxate(Octyl methoxycinnamate)	7.5%	Absorb	UVB	Thin oily liquid	Oils	Most commonly used sunscreen active
Benzophenones	Oxybenzone (benzophenone-3)	6%	Absorb	UVB/shorter wave UVA	Crystalline solid	Polar Oils	Potentially irritating, especially on face
Salicylates	Octisalate (Octylsalicylate)	5%	Absorb	UVB	Thin oily liquid	Oils	Weak UV absorber
	Homosalate	15%	Absorb	UVB	Thin oily liquid	Oils	Weak UV absorber
PABAs	Aminobenzoic Acid (PABA)	15%	Absorb	UVB	Crystalline solid	Water	Not widely used
	Octyldimethyl PABA (Padimate O)	8%	Absorb	UVB	Oily liquid	Oils	Not widely used
Physical Sunscreens	Titanium Dioxide	25%	Absorb and Scatter	UVB/UVA (dependent on particle size)	Insoluble powder	Insoluble	Can cause whitening on skin, especially if it blocks UVA Must be well dispersed to be effective
	Zinc Oxide	25%	Absorb and Scatter	UVB/UVA	Insoluble powder	Insoluble (except at low pH)	Can cause whitening on skin Must be well dispersed to be effective
Others	Octocrylene	10%	Absorb	UVB/shorter wave UVA	Viscous oily liquid	Oils	Photostabilizes avobenzone
	Ensulizole (Phenylbenzi midazole sulfonic acid)	4%	Absorb	UVB	Crystalline solid	Water	Highly efficient
	Avobenzone (Butyl methoxy dibenzoylmethane)	3%	Absorb	UVA	Crystalline solid	Polar oils	Generally poor photostability (stabilized by octocrylene)

products provide relatively similar UV protection, but the SPF 15 product will likely have better skin feel, and hence may be more likely to be used more often and at a higher dose per use.



Average level of sunscreen within labeled U.S. products sold in 2003. Increasing the SPF requires more and more sunscreen ingredients. Hence achieving an aesthetically pleasing product becomes more difficult at the higher SPF levels.[14]

A separate aesthetic negative that is often associated with inorganic sunscreens (titanium dioxide and zinc oxide) is the presence of a white film on the skin after application. To counter this effect the average particle size is reduced below the optimal light scattering size. These microfine grades are now commonly used in today's sunscreen formulations.

Measured Protection

It has been more than 40 years since "SPF" was introduced by Austrian scientist Franz Greiter as a standard measure of sun protection. SPF is the ratio of UV required to produce a perceptible redness, i.e., minimal erythema, on skin protected by sunscreen as compared to unprotected skin.[15] The skin's visual reddening response determines the **Minimal Erythemal Dose** or MED. SPF is impacted by the following factors: the light source including spectrum and intensity, sunscreen actives, the matrix or vehicle, application amount, and the biological response on the skin.

Beginning in the early 1980s, the highest SPF available was 15. Since then, the SPF in sunscreens has risen to as high as 50+. There is no upward limit to SPF in some countries. However, the U.S. FDA has recommended 30+ as the highest SPF.[16]

Few people can explain the differences between SPF numbers when asked. Most associate higher numbers with significantly greater protection and use the "higher is better" philosophy without understanding how this can impact the delivered efficacy.

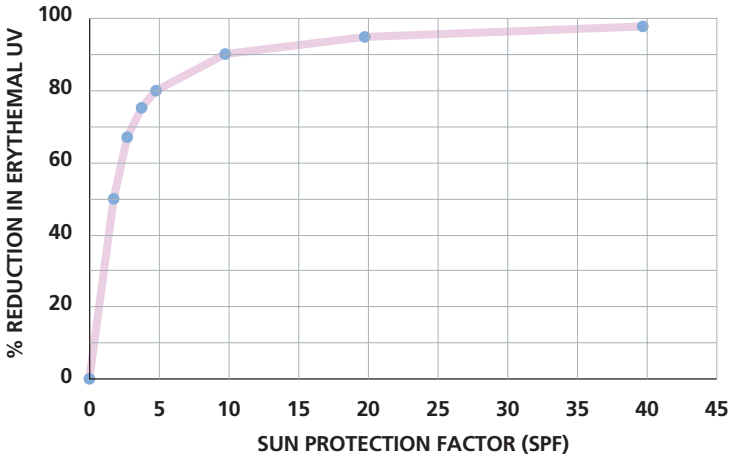
PROTECTION FACTORS: SO WHAT DO THEY REALLY MEAN?

SPF	FRACTION OF BURNING UV TRANSMITTED	TIME TO SUNBURN	BURNING UV BLOCKED
1	1/1 (all of it)	no change	0%
4	1/4	4x	75%
15	1/15	15x	93%
20	1/20	20x	95%
50	1/50	50x	98%

SPF is more complex than most people realize. The reality is that because protection factors are not linear, SPF 30 (97 percent UV block) and SPF 15 (93 percent UV block) differ only slightly. Applying two layers of lotion assures more even, continuous coverage, but it will also more than double the SPF. Additionally, applying half the effective application of an SPF 30 does not result in an SPF 15, but more likely an SPF between 7 and 9.

Safe Sun Practices

- Apply a broad-spectrum sunscreen daily with an SPF of at least 15. Apply the product liberally, uniformly and frequently.
- Reapply sunscreen every 2 hours when participating in outdoor activities, even on cloudy days.
- Avoid "peak" sunlight hours when the sun's rays are the strongest, from 10 a.m. until 4 p.m.
- Wear protective, tightly woven clothing, such as a long-sleeved shirt and pants.
- Wear a wide-brimmed hat and sunglasses when outdoors.
- Stay in the shade whenever possible.
- Avoid reflective surfaces (water, sand, concrete, snow), which can reflect up to 85 percent of the sun's damaging rays.
- No shadow... seek the shade! If your shadow is shorter than you are, you're likely to sunburn.
- Avoid tanning beds.
- Examine your skin head to toe at least once every three months to check for signs of skin cancer.



The protection delivered by the SPF is non-linear. This leads to diminishing returns at higher SPF numbers.

Emotional Attitudes & Behaviors

70 Percent Believe, 18 Percent Behave

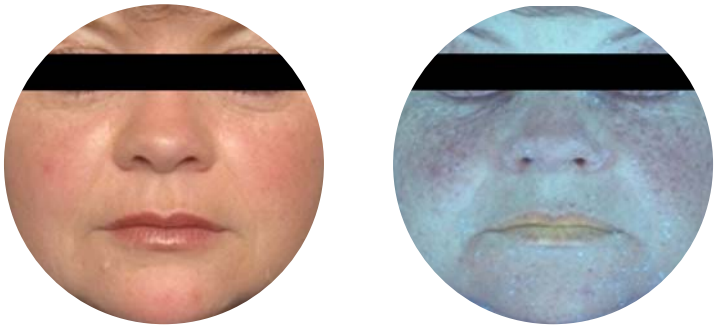
- **Consumers flirt with sun damage**:
  - 70 percent believe that sunlight causes premature aging, but only 18 percent use a daily UV moisturizer.
  - Less than 5 percent use recreational protection on a regular basis.
  - Even in summer, when the risk of burning is more obvious, only 58 percent of women report using sunscreen daily; while 26 percent never use a sunscreen.
  - In autumn, winter and spring, about 33 percent of women use sunscreen.
- **Most people underestimate their potential for UV damage** and don't realize that typical incidental radiation exposure averages 18 hours a week (indoor and out).[17]
- **88 percent of people say that they would use sunscreen** if they understood the risk of going without protection.
- **72 percent of physicians indicate patient compliance as the most important factor** in achieving sunscreen efficacy. 65 percent of physicians recommend daily protection.[18]

WHAT WORKS

New Beauty Intelligence

Skip Sunscreen Now, Pay Later

People who understand that they are at risk from skin cancer and aging are more motivated to protect themselves. According to a UV Exposure Survey,[19] once patients realize the extent of their unanticipated sun exposure, they agree to use sun protection regularly rather than just at the beach.



Visible cell damage may be avoidable (Wood's lamp photo)
Consistency of sunscreen use matters, but it is not instantly rewarded. Skin damage is cumulative. It happens gradually and the destruction only becomes visible with age. Patients who see their own incipient sun damage (right) are more motivated to protect their skin and minimize photodamage.

Intermittent use of sunscreen is not enough to protect skin from sun damage. Studies indicate that even modest increases in exposure adversely affect skin's function and appearance.

- In a study published by Phillips, et al.,[20] skipping sun protection on one day out of four was enough to lower the skin's defense mechanisms and increase endpoints related to photoaging, e.g., lysozyme staining.
- Skin expert Greg Hillebrand monitored photoaging in two cities with a 1.5 times difference in the annual average UVB exposure.[21] After one year, those exposed to higher radiation had aged visibly and had rougher, drier skin, larger and more age spots and had significantly more wrinkles.

A Little Dab Won't Do – Sunscreen Application in the Real World

Dermatologists encourage photoprotection. Studies show that people are aware of the risks, but few regularly use UV protection. Additionally, those who do use sunscreens regularly rarely apply the proper amount. Studies have found that people typically use only half the amount they need for full protection. This is believed to be a result of product aesthetics and having an incomplete understanding about SPF and what it really means.[22]

Properties that might be desirable at the beach (rub-proof and waterproof) would not be necessary in a daily facial moisturizer where aesthetics of the product are key and highly desirable. The formulator's art is in balancing efficacy and aesthetics.

To improve use, P&G Beauty scientists studied how human behavior affects efficacy. They observed that SPF products in lighter formulations tend to be used more regularly and applied more generously.[23]

The FDA standard dose for SPF testing is a sunscreen application of 2 mg/cm^2, which equals an estimated 28.47 grams of sunscreen to cover the entire body or the amount to fill a shot glass.[24]

Poorly formulated high-SPF products are frequently misused because they don't spread easily and feel heavy, occlusive, "hot" and greasy.

In a week-long, double-blinded sunscreen usage test comparing consumer application habits when using SPF 30 versus SPF 15, researchers found that:[25]

- Heavy feeling products with a higher SPF were applied much more sparingly
- Cosmetically formulated products with a lower SPF were used more consistently

Sunscreen Beauty (and Health!) Secrets

- **Aesthetics drives compliance.** Those using daily protection are more likely to consistently use facial moisturizers with an SPF 15 or 30 that readily "disappear" upon application.
- **Recreational products are best for beach time, sports or extreme sun exposure.** Though cosmetic products are preferable for daily use since they tend to have lighter, less greasy aesthetics, they are not waterproof or sweatproof. The correct water and rub resistant formulations should be used for extended sun exposure. Special care should be taken to reapply in order to achieve adequate protection.
- **Quantity and frequency of reapplication are the best protection.** Those requiring the highest level of protection or anticipating a high level of UV exposure need to apply sunscreen generously and then reapply sunscreen after dry down. This method provides a continuous and complete sunscreen film, helping to increase efficacy.

DID YOU KNOW?

Many Wrinkles in Time

- **Glass doesn't block UVA.** Glass filters UVB, but if light shines through, so does UVA.
- **High altitude increases solar radiation exposure.**
- **The two most effective UVA blockers in the U.S. are avobenzone**, a chemical that absorbs light, **and zinc oxide (ZnO)**, a mineral that scatters and absorbs light. These ingredients can be formulated for excellent skin feel as well as efficacy.
- **Titanium dioxide (TiO_2)** is also FDA-approved to block UVA. Efficacy delivered from titanium dioxide is formulation dependent. TiO_2 products can leave skin feeling coated and with a white appearance, which is not desirable.
- **Self tanners are not protective.** They develop color on the skin's surface via a chemical reaction.
- **The SPF number does not represent a specific length of time.** It represents a variable duration — the time it takes for skin to turn pink — which depends upon individual skin characteristics and intensity of exposure. Specifically, SPF equals the minimal erythemal dose with sunscreen divided by the minimal erythemal dose without sunscreen.

WHAT'S COMING

Promising New Areas

New Way to Improve UV Protection: the Critical Wavelength Method!

The frequency of sun protection failure raised the curiosity of P&G Beauty photobiologists. In July 2003, these researchers purchased 188 mass-market sunscreen products to evaluate the product claims and determine if the ingredients listed on the ingredient labels could support these claims.[26]

The analysis revealed:

- 90 percent of sunscreens now claim SPF 15 or higher, and 82 percent make UVA or broad-spectrum protection claims.
- 44 percent of those labeled "broad-spectrum" failed to provide the necessary breadth of protection required for the claim based on their lack of ingredients with FDA-approved UVA filters.
- Because sunscreen label claims are not always consistent with ingredients found to be protective, UVA testing and labeling needs to be standardized.

Based on these results, it is clear that many currently marketed sunscreen products primarily protect against UVB, with some coverage against UVA. Only those containing adequate levels of FDA-recognized long-wavelength UVA sunscreens should legitimately claim to provide "broad-spectrum" coverage. Ingredients that protect against UVA, including avobenzone and zinc oxide, fend off the higher wavelengths of UVA up to 400 nanometers.

Sunscreens are evaluated in terms of their ability to block mainly UVB via the SPF test. Erythema is used as the biological endpoint. However, we know that subclinical damage caused by UVA is also occurring and not being evaluated by this method. Both UVB and UVA need to be screened to guard the cutaneous immune system and avoid both acute and chronic cellular injury.

FIGURE A: BROAD-SPECTRUM PROTECTION

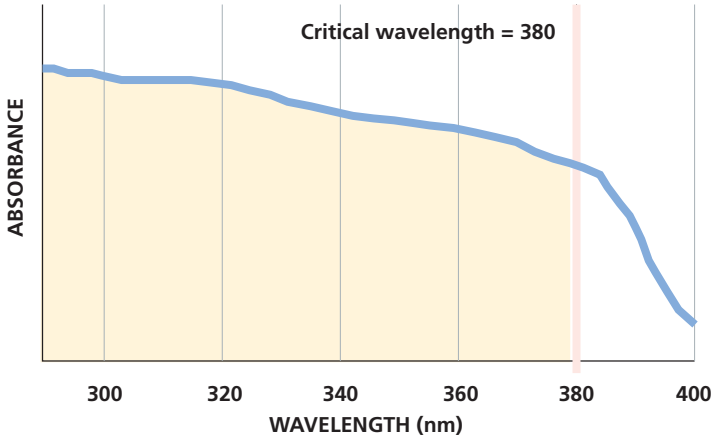
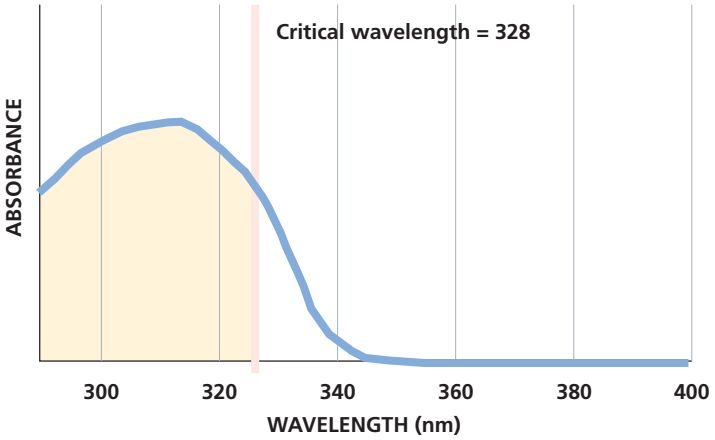


FIGURE B: UVB PROTECTION ONLY



Amplitude (height of the curve) *measures the degree to which a product absorbs UV, i.e., in vivo SPF.* **Breadth (width of the curve)** *reflects how broadly effective a product is across the UV spectrum. The wavelength below which 90% of the area under the whole absorption spectrum from 290 to 400 nm falls is the critical wavelength. The key is to cover more wavelengths with a broader, higher curve that delivers more UVA coverage, such as in Figure A.*[27]

Dermatologists and scientists agree that sunscreen marketers should supplement SPF information with data regarding UVA protection. This would give people a better idea about the total level of protection the products provide. Therefore, in addition to the FDA-required SPF test, P&G Beauty researchers have been subjecting their own UV moisturizers to a more comprehensive test that requires the formulas to protect skin from the breadth of ultraviolet light.

In working to close the UVA protection gap, P&G Beauty scientists have proposed that the FDA adopt the critical wavelength as a meaningful method to assess UVA efficacy and a simple label to communicate UVA protection. Critical wavelength, proposed as a standard measurement, would establish a more meaningful indication of broad-spectrum protection when combined with the SPF test. Establishing a standard of UVB/UVA filtration for sunscreens would improve and simplify skin protection.

In the current proposal to the FDA, for broad-spectrum/UVA claim, a product must have a critical wavelength of 370 nm. Figure A (left) shows how much coverage a "broad-spectrum" product should provide. Figure B (left) shows the coverage provided by a UVB sunscreen.

An absorbency curve that covers more wavelengths is the best way to characterize a sunscreen's broad-spectrum efficacy. Critical wavelength is a relevant and reproducible in-vitro index of the breadth of UV photoprotection, and when combined with in vivo SPF, provides a complete profile of sunscreen product efficacy.

SUMMARY

Not All SPF 15 Products Are Equal—But Daily Use Remains Important

When sunscreen technology was new, scientists assessed only the erythema endpoint or SPF. New research has shown that long-wavelength UVA can also cause skin damage. To this day, SPF lotions vary greatly in their broad-spectrum protection. Many SPF products claiming to reduce exposure to UVA do not even contain an FDA-recognized UVA sunscreen, such as avobenzone or zinc oxide. Currently, there is no universal test method or standard product label to indicate the level of UVA protection. Despite these variances in protection, experts still agree that everyone should practice sun-safe strategies, which include the daily use of an SPF 15 or higher product.

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AN ADDITIONAL TOOL

The UV Research Update CD holds a PowerPoint presentation of the charts and illustrations in this toolkit. Feel free to use these images. Please credit P&G Beauty.

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