



Any product marketed in the US as a sunscreen is considered an OTC drug and must contain approved active ingredients. The SPF must be determined in a panel of at least 20 human subjects, as outlined in the FDA Sunscreen Monograph.

The FDA Sunscreen Monograph

As of December 31, 2001, the FDA has delayed publication of part 352 and anticipates that the new effective date will not be before January 1, 2005. Part 352 will address formulation, labeling, and testing requirements for both UVA protection and UVB protection. See:

<http://www.fda.gov/OHRMS/DOCKETS/98fr/123101a.pdf>

The "Final" FDA Sunscreen Monograph was published in the Federal Register on Friday, May 21, 1999 (Vol 64, No 98, pages 27666-27693). Following is a synopsis:

General

- The FDA estimates that approximately 12,000 sunscreen SKU's will have to be relabeled, and some will need to be re-tested, within a 2-year period to comply with the requirements of the monograph. [p. 27684]

The FDA Monograph represents completion of the process of developing regulations for OTC sunscreen products initiated in August of 1978, except for "certain testing issues" and UVA labeling, which the FDA will discuss in future issues of the Federal Register. Until then, permissible UVA labeling must comply with the Tentative Final Monograph (May 12, 1993, 58 FR 28194) and its amendments (June 8, 1994, 59 FR 29706; September 16, 1996, 61 FR 48645; April 30 1997, 62 FR 23350 and October 22, 1998, 63 FR 56584).

Permitted Active Ingredients (Maximum Concentrations) [p. 27687]

- Aminobenzoic acid (15%)
- Avobenzene (3%)
- Cinoxate (3%)
- Dioxybenzone (3%)
- Homosalate (15%)
- Menthyl anthranilate (5%)
- Octocrylene (10%)
- Octyl methoxycinnamate (7.5%)
- Octyl salicylate (5%)

- Oxybenzone (6%)
- Padimate O (8%)
- Phenylbenzimidazole sulfonic acid (4%)
- Sulisobenzene (10%)
- Titanium dioxide (25%)
- Trolamine salicylate (12%)
- Zinc oxide (25%)

Products with Combinations of Active Ingredients [p. 27672]

- The concentration of each active ingredient must be sufficient to produce a minimum SPF of 2 [in the finished product].
- The finished product must have an SPF of not less than the number of active ingredients multiplied by 2.
 - * Zinc oxide may be used in combination with any monograph sunscreen active except avobenzene. [pp. 27680]

Labeling [pp. 27675-27677]

- The FDA has established 30 as an upper limit for SPF labeling. Products with SPF values over 30 may be labeled as “30 plus” or “30+”.
- The SPF value for a product labeled “water resistant” or “very water resistant” will be the SPF determined in the water resistance test.
- Extended wear claims concerning a specific number of hours of protection and the use of terms such as “all day protection” are not permitted.
- Permissible labeling is limited to prevention of sunburn.

Solar Simulators for SPF Determinations [p. 27690]

- Continuous emission spectrum from 290 to 400 nanometers similar to sunlight at sea level with the sun at a zenith angle of 10 degrees.
- Less than 1 percent total energy output from wavelengths shorter than 290 nanometers.
- Not more than 5 percent of total energy output from wavelengths longer than 400 nanometers.
- No significant time-related fluctuations in output.
- Beam uniformity within 10 percent.
- Output measured periodically with a calibrated spectroradiometer.

Subjects [pp. 27690-27691]

- Male and female with fair skin (Types I, II, and III, see below.)
- Good general health
- No medication that is known to produce abnormal sunlight responses
- No abnormal responses to sunlight, such as a phototoxic or photoallergic response
- No sunburn, suntan, scars, active dermal lesions or uneven skin tones on the areas of the back to be tested. (nevi, blemishes, or moles will be acceptable if in the physician’s judgment they will not interfere with the study results)
- Excess hair on the back is acceptable if the hair is clipped or shaved.
- Legally effective written informed consent
- Not more than 25 subjects, with the number fixed in advance by the investigator
- At least 20 subjects must produce valid data for analysis

Skin Types (From Sunburn and Tanning History based on first 30 to 45 minutes sun exposure after a winter season of no sun exposure.)

- I--Always burns easily; never tans (sensitive).
- II--Always burns easily; tans minimally (sensitive).
- III--Burns moderately; tans gradually (light brown) (normal).
- IV--Burns minimally; always tans well (moderate brown) (normal).
- V--Rarely burns; tans profusely (dark brown) (insensitive).
- VI--Never burns; deeply pigmented (insensitive).

Test Sites [pp. 27690-27691]

- Located on the back between the beltline and the shoulder blade and lateral to the midline
- A minimum of 50-square centimeters in area, outlined with ink, drawn with the subject in the test position, e.g. upright or supine

Application of test materials [p. 27691]

- 2 milligrams per square centimeter
- Spread using a finger cot
- Applied in a blinded, randomized manner
- If only one sunscreen drug product is being tested, UV radiation doses will be applied in a randomized manner.

Minimal Erythema Dose [p. 27687]

- The MED is the UV energy dose required to produce the first perceptible redness reaction with clearly defined borders on unprotected or protected skin.

Evaluation of Responses [p. 27691]

- The Evaluator must not be the same person who applied the test products or administered the doses of UV radiation.
- Erythema responses are evaluated 22 to 24 hours after exposure.
- The erythema responses should be evaluated using either a tungsten light bulb or a warm white fluorescent light bulb that provides a level of illumination at the test site within the range of 450 to 550 lux.
- Subjects should be in the same position used when the test site was irradiated.
- Some exposures should produce no effect; of those that produce an effect, the maximal exposure should be no more than twice the total energy of the minimal exposure.

Determination of the MED for Unprotected Skin [p. 27692]

- The MED for unprotected skin is determined by administering a geometric series of 5 exposures represented by $(1.25)^n$ e.g. 6, 8, 10, 13 and 16 seconds.
- Usually a preliminary MED series is administered on the day before the SPF test and the result determines the doses administered to unprotected and sunscreen-protected skin which are used to calculate the SPF.

Determination of Individual Subject SPF values [p. 27692]

- A series of 7 doses will be administered to the sunscreen-protected sites. Doses will be determined by the preliminary MED and the expected SPF of the product.
- For products with an expected SPF less than 8, the exposures will be the preliminary MED of unprotected skin times 0.64X, 0.80X, 0.90X, 1.00X, 1.10X, 1.25X, and 1.56X, where X equals the expected SPF of the test product.
- For products with an expected SPF between 8 and 15, the exposures will be the MED of unprotected skin times 0.69X, 0.83X, 0.91X, 1.00X, 1.09X, 1.20X, and 1.44X, where X equals the expected SPF of the test product.
- For products with an expected SPF greater than 15, the exposures will be the MED of unprotected skin times 0.76X, 0.87X, 0.93X, 1.00X, 1.07X, 1.15X, and 1.32X, where X equals the expected SPF.
- The SPF value of the test sunscreen is then calculated as the ratio of the MED of sunscreen-protected skin to the MED of unprotected skin.

Determination of the Test Product's SPF Value and PCD [p. 27692]

- Use SPF values from at least 20 test subjects.
- Compute the mean SPF value, \bar{x} , and the standard deviation, s .
- Find the upper 5-percent point from the t distribution, t .
- Compute $A = ts / \sqrt{n}$.
- The label SPF equals the largest whole number less than $(\bar{x} - A)$. {Typically, a product with a mean SPF of 15 would be labeled 13, by this approach.}
- Determine the Product Category designation: If $(30 + A) < \bar{x}$, the PCD is "High"; if $(12 + A) < \bar{x} < (30 + A)$, the PCD is "Moderate"; if $(2 + A) < \bar{x} < (12 + A)$, the PCD is "Minimal"; if $\bar{x} < (2 + A)$, the product shall not be labeled as a sunscreen drug product and shall not display an SPF value.

Water Resistant or Very Water Resistant. [pp. 27692-27693]

- An indoor pool, whirlpool, or jacuzzi maintained at 23 to 32 deg.C is used.
- The term "Very Water Resistant" replaces the current "Waterproof" category.
- For a "Water Resistant" product, the label SPF is the SPF value determined after 40 minutes of water immersion; for a "Very Water Resistant" product, the label SPF is the SPF value determined after 80 minutes of water immersion.