

Sun Protective Agents (Sunscreens): Part 2

Amount of Sunscreen for a Specific SPF

It is important to know that the efficacy of sunscreens are influenced by other ingredients in a formulation and that a certain concentration of a sunscreen in a product leads to different sun protection dependent on the type of skin, mode of application, and grade of UV exposure. Therefore, it is not possible to make a product with an exact SPF. It is always an approximate approach. If more than one sunscreens are combined in a product, determination of the SPF becomes even more difficult. Table 1 shows you examples of expected SPF values when sunscreens are used in oil-in-water emulsions such as creams and lotions.

FDA Regulations

FDA regulates sunscreens as over-the-counter (OTC) drugs. Cosmetic products that are marketed with sun-protection claims are regulated as both drugs and cosmetics. This means that sunprotective products are regulated differentially than „normal“ cosmetic products! Currently, certain but not all OTC drugs (that is, non-prescription drugs) that were marketed before the beginning of the OTC Drug Review may be marketed without specific approval pending publication of final regulations under the ongoing OTC Drug Review.

Once a regulation covering a specific class of OTC drugs is final, those drugs must either be the subject of an approved New Drug Application (NDA), or comply with the appropriate monograph for an OTC drug. These monographs, which are published in the Federal Register, state requirements for categories of non-prescription drugs,

such as what ingredients may be used and for what intended use. There are monographs for sunscreens, acne medications, treatments for dandruff, seborrheic dermatitis, and psoriasis. The monograph for OTC sunscreen drug products (21CFR 352), published on 05/21/1999, addresses the testing and labeling of sunscreen products for the prevention of sunburn (that is, UVB radiation protection).

Table 2: Maximum Concentrations Allowed by Federal Authorities

	USA (FDA)		Europe (EEC)	Japan
	If used alone	If combined	If used alone	If used alone
Para-Aminobenzoid Acid (PABA)	15 %	-	5 %	-
Cinoxate	3 %	1-3 %	5 %	5 %
Dioxybenzone	3 %	3 %	-	-
Homosalate	15 %	4-15 %	10 %	10 %
Menthyl Anthranilate	5 %	3.5-5 %	-	-
Octocrylene	10 %	7-10 %	10 %	-
Octyl Methoxycinnamate	7.5 %	2-7.5 %	10 %	-
Octyl Salicylate	5 %	3-5 %	5 %	10 %
Oxybenzone	6 %	2-6 %	10 %	-
Phenylbenzimidazole Sulfonic Acid	4 %	1-4 %	8 %	-
Sulisobenzone	10 %	5-10 %	-	-
Titanium Dioxide	25 %	2-25 %	-	no limit
Zinc Oxide	25 %	2-25 %	-	no limit

DISCLAIMER: We can not take responsibility on the accuracy and correctness of these numbers. For further information please refer directly to the corresponding authority.

Table1: Concentration of Sunscreens & SPF

	Low SPF 2-5	Moderate SPF 6-11	High SPF 12-19	Ultra High SPF >20
Titanium Dioxide	<4 %	8 %	12 %	20 %
Titanium Dioxide, Micronized	2 %	4 %	6 %	10 %
Zinc Oxide	5 %	10 %	15 %	25 %
Zinc Oxide, Micronized	3 %	7.5 %	12 %	20 %
Octyl Methoxycinnamate (OM-Cinnamate)	2 %	4 %	7.5 %	-

Examples of 2 Combinations

Zinc Oxide, Micronized + Titanium Dioxide	5 + 5 %
OM-Cinnamate + Titanium Dioxide, Micronized	5 + 4 %
OM-Cinnamate + Zinc Oxide, Micronized	7.5 + 5 %
OM-Cinnamate + Octyl Salicylate	7.5 + 5 %
OM-Cinnamate + Octyl Salicylate	7.5 + 5 %

Examples of 3 Combinations

OM-Cinnamate + Zinc Oxide, Micronized + Titanium Dioxide	7.5 + 5 + 5 %
OM-Cinnamate + Octyl Salicylate + Benzophenone-3	7.5 + 5 + 6 %
OM-Cinnamate + Zinc Oxide, Micronized + Octyl Salicylate	7.5 + 7.5 + 5 %

DISCLAIMER: The information contained in this chart is based upon opinion, observation, and/or research unrelated in any way to Somerset Cosmetic Company. No representation is made, herein, as to its accuracy or the method by which it was derived. This chart may or may not be relevant for any particular product, and is only intended to provide information, which in our opinion, might be valuable when used as such. We make no conclusions or recommendations about other companies or products that use this chart. Numbers = wgt%

The effective date for manufacturers to comply with the requirements of the monograph was subsequently delayed until 12/31/2002. FDA intends to publish a proposal to amend the sunscreen monograph to develop a comprehensive monograph that addresses formulation, labeling, and testing requirements for both UVB and UVA radiation protection. Following that publication, there will be a public comment period and FDA will prepare an amended final monograph for publication in a future issue of the Federal Register.

Where to learn more about NDAs and OTC monographs?

If you have questions about NDAs and OTC monographs, you should address them to CDER (Center for Drug Evaluation & Research). The CDER Handbook provides an introduction to the drug approval and OTC monograph processes. Other resources, also available on CDER's Web site (<http://www.fda.gov/cder>), provide additional information on these subjects.

Sources:
Information about Suntan Products, Sunscreens, and Tanning at: <http://www.cfsan.fda.gov/~dms/cos-sun.html>