

Guideline for Selling Sunscreen Products in the US

In June 2011, the U.S. Food and Drug Administration (FDA) announced new requirements for the labeling of over-the-counter (OTC) sunscreen products. For most OTC sunscreen products, the final rules were scheduled to go into effect on June 18, 2012. Key requirements under the final rule are as follows:

- **Broad Spectrum designation:** Sunscreens should provide protection against both ultraviolet A radiation (UVA) and ultraviolet B radiation (UVB) to be classified as “Broad Spectrum”. Only products that make broad spectrum claims that they decrease the risk of skin cancer or premature skin aging are subject to these requirements.
- **Use claims:** Broad spectrum sunscreens with an SPF value of 15 or higher can claim to: *‘reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures.’* Sunscreen products that are not broad spectrum, or that are broad spectrum with SPF values from 2 to 14, can only claim *‘help prevent sunburn’*. Also, they would require a warning statement that reads: *“Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.”*
- **Prohibited claims:** Claims such as “waterproof”, “sweatproof”, “sunblock”, “all-day”, “extended wear”, and “instant-protections” are not permitted.
- **Water Resistant claims:** “Water-resistant” claims are permitted. If this term is used, it should be indicated whether the sunscreen will remain effective for 40 or 80 minutes while swimming or sweating, based on standard testing.
- **Drug Facts:** All sunscreens must indicate standard “Drug Facts” information on the back and/or side of the container.
- **SPF testing:** The final rule requires that labeling for covered OTC sunscreen products bear the SPF values determined in accordance with the new SPF testing requirements, which measure protection against sunburn caused by UVB radiation. FDA has allowed an additional year for manufacturers to test in accordance with the new SPF testing requirements.
- **SPF Claims:** In addition to the above final regulations, in June 2011 the FDA proposed a regulation that would limit the maximum SPF value on sunscreen labeling to “SPF 50+”
- **Other Requirements**
 - Manufacturer has to be a registered drug establishment with the FDA and comply with cGMP regulations for drug manufacturing
 - Labeling has to comply with labeling requirements for OTC drugs, including Drug Facts format labeling
 - Final product has to be listed with the FDA's NDC database (National Drug Code Directory) by the manufacturer or the distributor
 - Product has to have efficacy testing on the formula to show that it delivers the SPF that the label claims. Additional tests are warranted if you want to make broad spectrum protection claims
 - Safety testing to prove that the product is safe, usually a repeated insult patch test (RIPT) on humans volunteer subjects needs to be done
 - Stability testing will have to be conducted, including periodic assays of the active ingredients, to show that the active ingredients don't deteriorate over time

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Labeling Requirements for Sunscreen Products only	Outer Box		Inner Container	
	Front	Side	Front	Side
Brand Name	X		X	
Product Description as “Sunscreen” in BOLD	X		X	
State “Broad Spectrum SPF value”	X		X	
Water Resistance Statements if claimed “Water Resistant (40 minutes)” Or “Water Resistant (80 minutes)”	X		X	
Net Quantity of Contents – at bottom 30% of the PDP and Prominence and in BOLD (Pound and ounce required. May additionally be stated also in the metric system)	X		X	
Name of the active ingredient ^{*1} and statement of identity such as “ Purpose Sunscreen”		X		X
Uses: Use the below statement for products with SPF rating 15 and over <ul style="list-style-type: none"> • Helps prevent sunburn • if used as directed with other sun protection measures (<i>see Directions</i>) 		X		X
Warnings. SPF 15 and over: Under the heading the following must appear <ul style="list-style-type: none"> • Do not use on damaged or broken skin. • When using this product, keep out of eyes. Rinse with water to remove. • Stop use and ask a doctor if rash occurs SPF 2 to less than 15: Under the heading the following must appear Skin Cancer/Skin Aging Alert; Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.		X		X
Directions. For all sunscreen products: <ul style="list-style-type: none"> • apply liberally (or generously). Option to add “and evenly 15 minutes before sun exposure.” • apply to all skin exposed to the sun [optional statement] • children under 6 months of age: Ask a doctor SPF value of 15 or higher: Use the below statement Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or 19 higher and other sun protection measures including: <ul style="list-style-type: none"> • limit time in the sun, especially from 10 a.m.-2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses For products that satisfy the water resistance test: Use the below statement <ul style="list-style-type: none"> • reapply: <ul style="list-style-type: none"> • after 40 minutes (or 80 minutes) of swimming or sweating • immediately after towel drying • at least every 2 hours. For products that do not satisfy the water resistance test: Use the below statement <ul style="list-style-type: none"> • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating 		X		X
Business Address: Street name, city, state and zip code of Business - manufacturer, packer or distributor. For US address, street name can be omitted if business name is in telephone directories.		X		X
Inactive Ingredients – Declaration in descending order of predominance except flavor, fragrance, and trade secret ingredients Color Additive – Should be FDA approved names.		X		X
Country of Origin		X		X
Other information: optional				

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All of the above are translated into English		X	X	X	X
Font Size	Ingredients: 1/16", 1/32" (Labeling surface, less than 12 sq. in.)	X	X	X	X
	Net Contents: <ul style="list-style-type: none"> • 1/16" (PDP less than 5 sq. in.) • 1/8" (PDP 5-25 sq. in.) • 3/16" (PDP 25-100 sq. in.) 	X	X	X	X
	Warning: 1/16"	X	X	X	X
	All Others: Reasonably related to panel size	X	X	X	X
Background Contrast - conspicuous and easily readable		X	X	X	X
Obscuring Designs, Vignettes: not obscured by vignettes or other designs		X	X	X	X

*1 This applies to sunscreen products containing aminobenzoic acid, avobenzone, cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, oxybenzone, padimate O, sulisobenzene, titanium dioxide, trolamine salicylate, or zinc oxide, alone or in combination are covered.

text MUST NOT run over dashed line above (r&l: 2 mm)



natural protection

100% naturally sourced sunscreen ingredients

lotion sunscreen

BROAD SPECTRUM SPF 50

DERMATOLOGIST RECOMMENDED

NET WT. 3 OZ. (85 g)

AVEENO® Natural Protection Lotion
Sunscreen with Broad Spectrum SPF 50 contains 100% naturally sourced sunscreen ingredients, a more natural alternative. It forms a protective barrier on top of skin that scatters both UVA and UVB rays. Developed in partnership with leading dermatologists, this extra gentle formula with skin-soothing ACTIVE NATURALS® oat is specially designed for sensitive skin.
fragrance-free • water resistant • hypoallergenic • oil-free

Drug Facts	Purpose
Active Ingredients Titanium Dioxide (6%), Zinc Oxide (3%)	Sunscreen
Uses • helps prevent sunburn • if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.	
Warnings For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • apply generously and evenly 15 minutes before sun exposure • reapply: after 80 minutes of swimming or sweating, immediately after towel drying, at least every 2 hours • Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. – 2 p.m., wear long-sleeved shirts, pants, hats, and sunglasses, children under 6 months of age. Ask a doctor	
Other Information • protect this product from excessive heat and direct sun • may stain some fabrics	
Inactive Ingredients Water, C-12-15 Alkyl Benzoate, Cetyl Dimethicone, Styrene/Acrylates Copolymer, PEG-8, Beeswax, Dimethylimidazolidinone Rice Starch, Polyamide-5, Butylene Glycol, Ethylhexylglycerin, Glyceryl Stearate, PEG-100 Stearate, Benzyl Alcohol, Dimethicone, Polyhydroxystearic Acid, Arachidyl Alcohol, Caprylyl Glycol, Trisiloxane, Dipropylene Glycol Dibenzate, Glycerin, Pentylene Glycol, Behenyl Alcohol, Triethoxycaprylylsilane, Xanthan Gum, Citric Acid, Bisabolol, Acrylates/Dimethicone Copolymer, Arachidyl Glucoside, PPG-15 Stearyl Ether Benzoate, Chlorophenesin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Squalane, Dipotassium Glycyrrhizate, Polyaminopropyl Biguanide, Sodium Citrate, Hydroxyphenyl Propamidobenzoic Acid, Polysorbate 60, Avena Sativa (Oat) Kernel Extract	

Questions?
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