



SUNSCREEN 101

SUMMER 2008

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SUNSCREEN LABELS ARE CHANGING!

THE FDA IS UPDATING THE STANDARDS FOR TESTING, FORMULATING AND LABELING SUNSCREEN PRODUCTS TO INCLUDE UVA PROTECTIVE INFORMATION, NEW SPF TESTING PROCEDURES, AND MORE COMBINATIONS OF ACTIVE SUNSCREENS IN PRODUCTS. THERE ARE CURRENTLY NO SET INTERNATIONAL STANDARDS FOR RATING SUNSCREEN PRODUCTS AND THE UNITED STATES IS ONLY ONE OF A FEW COUNTRIES THAT WILL RECOGNIZE UVA PROTECTION. BY CHANGING PRODUCT LABELS, THE FDA BELIEVES CONSUMERS WILL MORE EASILY UNDERSTAND HOW MUCH PROTECTION THEY ARE GETTING AND MINIMIZE CONFUSION BETWEEN VARIOUS PRODUCTS. THE NEW RULE WILL ADD:

- NEW COMBINATIONS OF INGREDIENTS
- UVA EFFECTIVENESS TESTING AND LABELING
- INCREASE THE HIGHEST SPF VALUES FROM 30+ TO 50+
- REQUIRE A "SUN ALERT" STATEMENT
- EMPHASIZE REAPPLYING SUNSCREEN OFTEN, REGARDLESS OF SPF VALUE
- MINOR REVISIONS TO EXISTING SPF (UVB) TESTING PROCEDURES
- "WARNINGS" STATEMENT REQUIREMENT IN THE "DRUG FACTS" BOX

Special Interest Articles:

- ACTIVE INGREDIENTS
- NEW LABELS
- PRODUCT COMPARISONS

WHAT IS UVA & UVB?

UVA AND UVB ARE ULTRAVIOLET SUNLIGHT THAT WE CANNOT SEE. UVA LIGHT, WAVELENGTHS OF 320-400 NM, IS RESPONSIBLE FOR **TANNING** AND **PREMATURE AGING** OF THE SKIN BECAUSE IT PENETRATES THE SKIN MORE THAN UVB LIGHT. UVB LIGHT, WAVELENGTHS 290-320 NM, CAUSES **SUNBURNS**. UVA CAN BE FURTHER DIVIDED INTO UVA-I, OR **FAR** UVA (340-400 NM), AND UVA-II, OR **NEAR** UVA (320-340 NM). BOTH TYPES OF LIGHT DAMAGE THE SKIN AND INCREASE THE RISK OF SKIN CANCER.



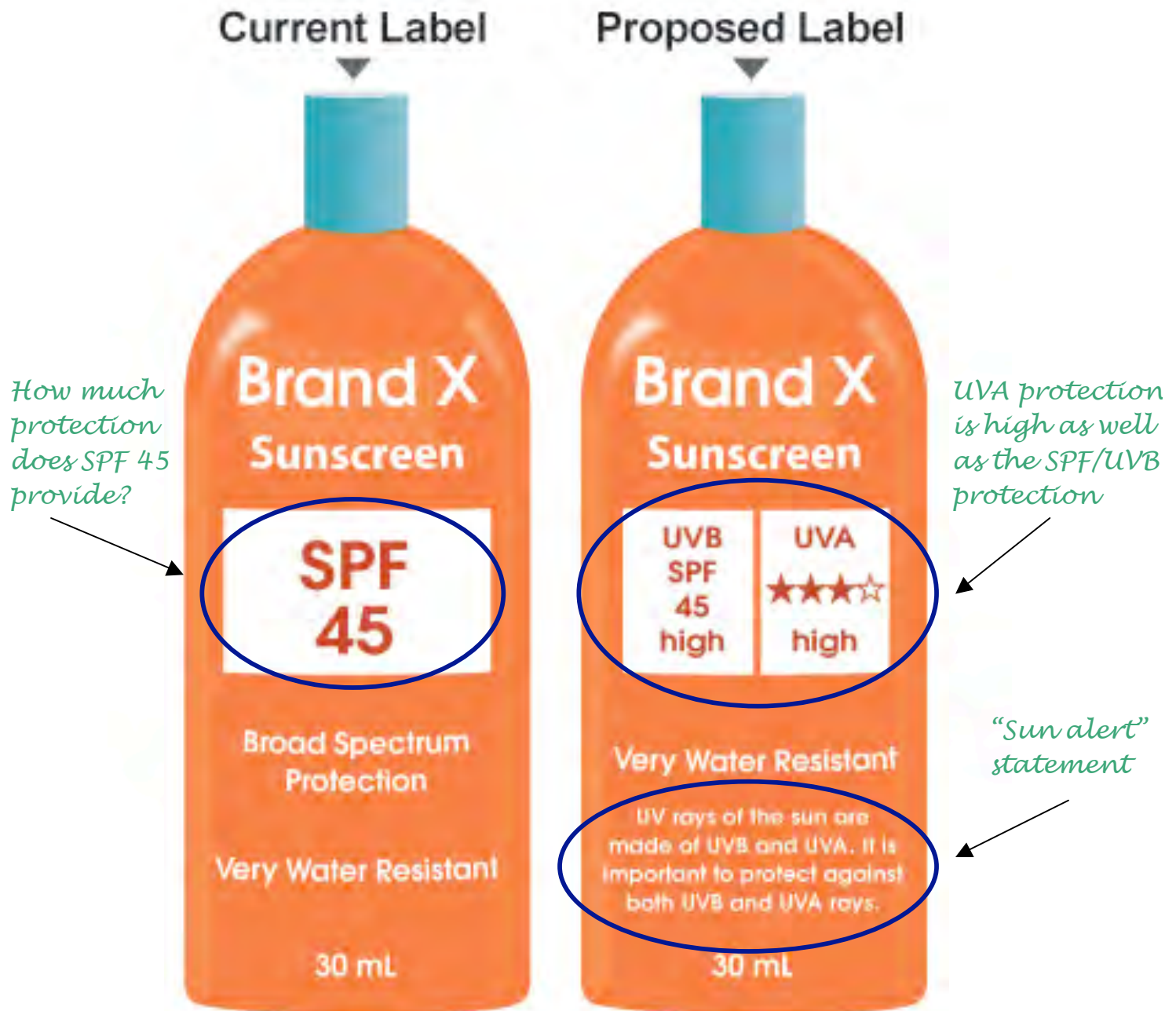
ACTIVE INGREDIENTS AND COVERAGES

UVB LIGHT IS 1000 TIMES MORE POTENT THAN UVA LIGHT, WHICH IS WHY UVB CAUSES BURNING.

<i>Drug Name</i>	<i>Concentration, %</i>	<i>Absorbance</i>
AMINO BENZOIC ACID	UP TO 15	UVB
AVOBENZONE	2-3	UVA-I
CINOXATE	UP TO 3	UVB
DIOXYBENZONE	UP TO 3	UVB, UVA-II
ECAMSULE	2	UVA-II
ENSULIZOLE	UP TO 4	UVB
HOMOSALATE	UP TO 15	UVB
MERADIMATE	UP TO 5	UVA-II
OCTOCRYLENE	UP TO 10	UVB
OCTINOXATE	UP TO 7.5	UVB
OCTISALATE	UP TO 5	UVB
OXYBENZONE	UP TO 6	UVB, UVA-II
PADIMATE O	UP TO 8	UVB
SULISOBENZONE	UP TO 10	UVB, UVA-II
TITANIUM DIOXIDE	2 TO 25	PHYSICAL
TROLAMINE SALICYLATE	UP TO 12	UVB
ZINC OXIDE	2 TO 20	PHYSICAL



WHAT THE NEW LABELS WILL LOOK LIKE



It isn't the SPF in the sunscreen, but rather how well and how often the sunscreen is applied that provides us the most protection from the sun

THE NEW UVA RATING SYSTEM USES STARS TO INDICATE LOW, MEDIUM, HIGH, OR HIGHEST PROTECTION WHICH IS ALSO INDICATED RIGHT ON THE LABEL. THE FDA BELIEVES THE STAR SYSTEM WILL BE EASIER FOR THE CONSUMER TO UNDERSTAND BECAUSE SEVERAL OTHER THINGS ARE ALREADY RATED ACCORDING TO STARS (HOTELS AND RESTAURANTS).

<i>Star Category</i>	<i>Category Description</i>
★ ☆ ☆ ☆	<i>Low</i>
★ ★ ☆ ☆	<i>Medium</i>
★ ★ ★ ☆	<i>High</i>
★ ★ ★ ★	<i>Highest</i>

SUNSCREEN LABELS WILL NO LONGER INCLUDE THE WORDS “**WATERPROOF**”, “**SWEATPROOF**”, OR “**SUNBLOCK**” BECAUSE NO PRODUCT IS TRULY WATER OR SWEAT “PROOF”, ONLY WATER OR SWEAT “RESISTANT”. THE FDA HAS PROPOSED THAT LABELS INCLUDE THE FOLLOWING INSTEAD:

- **NOT WATER RESISTANT** – “REAPPLY AT LEAST EVERY 2 HOURS AND AFTER TOWEL DRYING, SWIMMING, OR SWEATING.”
- **WATER/SWEAT RESISTANT** - “REAPPLY AFTER 40 MINUTES OF SWIMMING OR SWEATING, AND AFTER TOWEL DRYING. OTHERWISE, REAPPLY AT LEAST EVERY 2 HOURS.”
- **VERY WATER/SWEAT RESISTANT** – “REAPPLY AFTER 80 MINUTES OF SWIMMING OR SWEATING, AND AFTER TOWEL DRYING. OTHERWISE, REAPPLY AT LEAST EVERY 2 HOURS.”

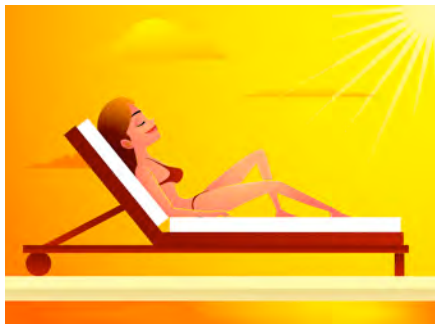


NEW "DRUG FACTS" LABEL

Active ingredients and percentages clearly identified

Drug Facts	
Active ingredients Avobenzone 3% Homosalate 10% Octinoxate 7.5%	PurposeSunscreen
Uses ■ high UVB sunburn/UVA protection ■ for skin highly sensitive to sunburn ■ retains SPF after 80 minutes of activity in the water	
Warnings For external use only UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.	
When using this product keep out of eyes. Rinse with water to remove.	
Stop use and ask a doctor if skin rash occurs	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Directions ■ apply liberally before sun exposure ■ apply and reapply as directed to avoid lowering protection ■ reapply after 80 minutes of swimming or sweating and after towel drying. Otherwise, reapply at least every 2 hours. ■ children under 6 months: ask a doctor	
Inactive ingredients alphabetical listing of ingredients	
Questions or comments? call toll free 1-800-XXX-XXXX	

More specific directions on how often to apply, depending on what activities you are doing.





POPULAR PRODUCTS



Aveeno Baby, SPF 55

-AVOBENZONE 3%, HOMOSALATE 10%, OCTISALATE 5%, OCTOCRYLENE 2.8%, OXYBENZONE 6%

Banana Boat Sport, SPF 30 “ULTRA SWEATPROOF”

-OCTINOXATE 7.5%, OXYBENZONE 5.25%, OCTISALATE 4.75%,
TITANIUM DIOXIDE 1.2%

Banana Boat Kids Tear Free, SPF 50 “WATERPROOF PEDIATRICIAN TESTED LONG LASTING PROTECTION”

-HOMOSALATE 15%, OCTINOXATE 7.5%, OCTISALATE 5%, TITANIUM DIOXIDE 2.4%

Coppertone, SPF 4 “WATERPROOF”

-OCTOCRYLENE, OCTINOXATE (NO PERCENTAGES GIVEN ON BOTTLE OR WEBSITE)

Coppertone, SPF 8 “WATERPROOF”

-OCTINOXATE, OXYBENZONE (NO PERCENTAGES GIVEN ON BOTTLE OR WEBSITE)

Coppertone, SPF 30 “SUNBLOCK LOTION, WATERPROOF”

-AVOBENZONE, HOMOSALATE, OCTISALATE, OCTOCRYLENE, OXYBENZONE (NO PERCENTAGES GIVEN ON BOTTLE OR WEBSITE)

Coppertone Sport Quick Cover Lotion Spray, SPF 30 “ULTRA SWEATPROOF/WATERPROOF”

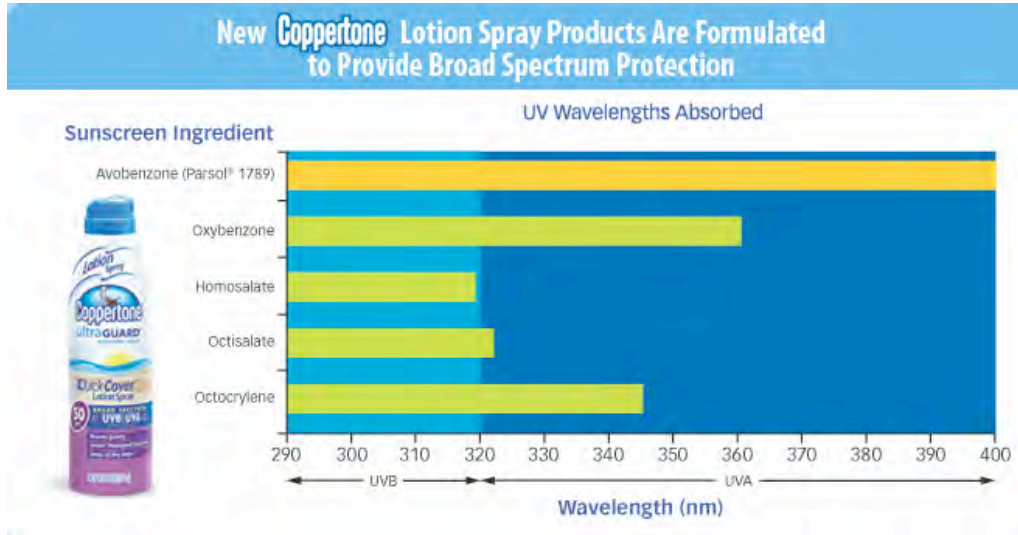
-AVOBENZONE 2%, HOMOSALATE 10%, OCTISALATE 5%, OCTOCRYLENE 4%, OXYBENZONE 4%

Coppertone Sport, SPF 50 “ULTRA SWEATPROOF/WATERPROOF”

-AVOBENZONE 3%, HOMOSALATE 13%, OCTISALATE 5%, OCTOCRYLENE 5%, OXYBENZONE 6%

Coppertone Water Babies, SPF 50 "WATERPROOF – NO 1. PEDIATRICIAN RECOMMENDED BRAND"

-AVOBENZONE 3%, HOMOSALATE 13%, OCTISALATE 5%, OCTOCRYLENE 7%, OXYBENZONE 4%



Neat chart on Coppertone's website comparing absorbencies of active ingredients

Skin Effects Active Sunscreen Lotion with Dermaplex Technology, SPF 30 "VERY WATER/SWEAT RESISTANT"

-AVOBENZONE 1%, OCTOCRYLENE 6%, OXYBENZONE 3.5%

Skin Effects Sunscreen Lotion with Dermaplex Technology, SPF 60 (NOT WATER/SWEAT RESISTANT)

-AVOBENZONE 1%, OCTOCRYLENE 8%, OXYBENZONE 3.5%

Vanicream Sunscreen Sport, SPF 35

-ZINC OXIDE 8%, OCTINOXATE 7.5%

Vanicream Sunscreen Sensitive Skin, SPF 60

-TITANIUM DIOXIDE 7.5%, ZINC OXIDE 7.5%

****Store brands also contain the same ingredients as their brand equivalents, so these are a less expensive option for great sun protection****

DON'T JUST WEAR SUNSCREEN!



- GO INSIDE DURING MIDDAY (NOON – 2 PM)
- WEAR A SHIRT OR COVER-UP
- WEAR A WIDE BRIMMED HAT TO COVER NECK AND EARS
- WEAR SUNGLASSES, NO MATTER HOW YOUNG, TO PROTECT EYES FROM SUN DAMAGE
 - CHILDREN USUALLY SPEND MORE TIME OUTDOORS = MORE SUN EXPOSURE
- ***DON'T THINK HIGHER SPF AND UVA PROTECTION MEANS LESS FREQUENT APPLICATIONS - YOU CAN NEVER APPLY TOO MUCH SUNSCREEN!***

WHEN WILL A FINAL RULE BE PUBLISHED?

WHILE THE FDA HAS MADE NO ANNOUNCEMENT FOR THE DATE THE NEW RULES WILL GO INTO EFFECT, DISCUSSION OF COMMENTS ON THE SUBJECT ENDED DECEMBER 27, 2007. CHANGES MAY BE EXPECTED FOR THE SUMMER OF 2009. KEEP YOURSELF UP-TO-DATE ON OTHER SUBJECT BY VISITING THE FOLLOWING REFERENCES FOR MORE INFORMATION...

WWW.FDA.GOV

WWW.EMEDICINE.COM/DERM/TOPID510.HTM

WWW.COPPERTONE.COM

WWW.NLM.NIH.GOV/MEDLINEPLUS



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