

COPPERTONE TANNING SUNSCREEN SPF 8- avobenzone 2%, homosalate 5%, octisalate 4.5%, octocrylene 3% lotion
Beiersdorf Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Coppertone Tanning Lotion SPF 8

Drug Facts

Active ingredients

Avobenzone 2%, Homosalate 5%, Octisalate 4.5%, Octocrylene 3%

Purpose

Sunscreen

Use

- helps prevent sunburn

Warnings

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.

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying

- at least every 2 hours
- children under 6 months: Ask a doctor

Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics or surfaces

Inactive ingredients

water, aluminum starch octenylsuccinate, glycerin, silica, phenoxyethanol, isododecane, ethylhexylglycerin, polyester-27, styrene/acrylates copolymer, acrylates/C10-30 alkyl acrylate crosspolymer, arachidyl alcohol, neopentyl glycol diheptanoate, glyceryl stearate, PEG-100 stearate, tocopherol, beeswax, fragrance, behenyl alcohol, arachidyl glucoside, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate

Questions

1-866-288-3330

Coppertone[®] Sunscreen Lotion

Tanning

Lightweight & Moisturizing 8

No Dyes, PABA, Oxybenzone

Water Resistant (80 Minutes)

Broad Spectrum SPF 8

8 FL OZ (237 mL)



COPPERTONE TANNING SUNSCREEN SPF 8

avobenzone 2%, homosalate 5%, octisalate 4.5%, octocrylene 3% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66800-4086
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
ISODODECANE (UNII: A8289P68Y2)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POTASSIUM HYDROXIDE (UNII: WZ3H3C48M4T)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	

POLYESTER-7 (UNII: 0841698D2F)
DOCOSANOL (UNII: 9G1OE216XY)
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q3OS3)
TOCOPHEROL (UNII: ROZB2556P8)
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
PEG-100 STEARATE (UNII: YD01N1999R)
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)

Product Characteristics

Color	white (White to Off-White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66800-4086-1	237 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/03/2020	

Labeler - Beiersdorf Inc (001177906)