COPPERTONE OIL FREE SUNSCREEN SPF 30- avobenzone 3%, homosalate 8%, octisalate 4.5%, octocrylene 6% 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 Oil Free Lotion SPF 30

Drug Facts

Active ingredients

Avobenzone 3%, Homosalate 8%, Octisalate 4.5%, Octocrylene 6%

Purpose

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 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

- 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-sleeve shirts, pants, hats, and sunglasses
- 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, polyester-27, silica, styrene/acrylates copolymer, phenoxyethanol, isododecane, arachidyl alcohol, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, neopentyl glycol diheptanoate, behenyl alcohol, tocopherol, beeswax, arachidyl glucoside, potassium hydroxide, glyceryl stearate, PEG-100 stearate, disodium EDTA, sodium ascorbyl phosphate

Coppertone ® Sunscreen Lotion

Oil Free Face

Defend & Care

30

Won't Clog Pores or Cause Breakouts

Free Of oxybenzone, octinoxate, dyes & PABA

Water Resistant (80 Minutes)

Broad Specturm SPF 30

3 FL OZ (88 mL)



COPPERTONE OIL FREE SUNSCREEN SPF 30

avobenzone 3%, homosalate 8%, octisalate 4.5%, octocrylene 6% lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66800-3900
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 g in 100 g	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	3 g in 100 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 g in 100 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)			
DOCOSANOL (UNII: 9G10E216XY)			
TOCOPHEROL (UNII: R0ZB2556P8)			

GLYCERYL STEARATE SE (UNII: FCZ5MH785I) DISODIUM EDTA-COPPER (UNII: 6V475AX06U) **SODIUM ASCORBYL PHOSPHATE** (UNII: 836SJG51DR) ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU) CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) WATER (UNII: 059QF0KO0R) STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A) PHENOXYETHANOL (UNII: HIE492ZZ3T) ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ) **SYNTHETIC BEESWAX** (UNII: 08MNR5YE2R) POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) PEG-100 STEARATE (UNII: YD01N1999R) **GLYCERIN** (UNII: PDC6A3C0OX) **ALUMINUM STARCH OCTENYLSUCCINATE** (UNII: 19PJ0O6294) POLYESTER-7 (UNII: 0841698D2F) ISODODECANE (UNII: A8289P68Y2)

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Ш	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:66800- 3900-3	88 g in 1 TUBE; Type 0: Not a Combination Product	02/01/2022		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	02/01/2022		

Labeler - Beiersdorf Inc (001177906)

Revised: 3/2023 Beiersdorf Inc