COPPERTONE OIL FREE SPF 50 SUNSCREEN- avobenzone 3%, homosalate 10%, octisalate 4.5%, octocrylene 8% 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 50

Drug Facts

Active ingredients

Avobenzone 3%, Homosalate 10%, Octisalate 4.5%, Octocrylene 8%

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

Questions?

1-866-288-3330

Coppertone® Sunscreen Lotion

Oil Free FACE

50

Won't clog pores or cause breaksouts

Free of oxybenzone, octinoxate, dyes & PABA

Water Resistant (80 Minutes)

Broad Spectrum SPF 50

3 FL OZ (88 mL)





OIL FREE

WON'T CLOG PORES OR CAUSE BREAKOUTS

Free of oxybenzone, octinoxate, dyes & PABA

Water Resistant (80 Minutes) **Broad Spectrum SPF 50**

3 FL OZ (88 mL)

Broad Spectrum UVA/UVB protection specially formulated for the face



Hypoallergenic Fragrance Free Lightweight

Drug Facts

Active ingredients

Avobenzone 3%, Homosalate 10%,

Purpose Sunscreen

Octisalate 4.5%, Octocrylene 8% **Uses** helps prevent sunburn sun protection measures (see **Directions**), decreases the risk of skin

if used as directed with other 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:

 | Imit 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 may stain or damage some fabrics or surfaces and direct sun

Inactive ingredients water, aluminum starch octenylsuccinate, styrene/acrylates copolymer, glycerin, polyester-27, silica, phenoxyethanol, isododecane, arachidyl alcohol, beeswax, ethylhexylglycerin, neopentyl glycol diheptanoate, behenyl alcohol, tocopherol, acrylates/C10-30 alkyl

acrylate crosspolymer, arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate

Questions? 1-866-288-3330

www.coppertone.com

Beiersdorf

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COPPERTONE OIL FREE SPF 50 SUNSCREEN

avobenzone 3%, homosalate 10%, octisalate 4.5%, octocrylene 8% lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66800-4094

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	3 g in 100 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	10 g in 100 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)	
TOCOPHEROL (UNII: ROZB2556P8)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
POLYESTER-7 (UNII: 0841698D2F)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
DOCOSANOL (UNII: 9G10E216XY)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISODODECANE (UNII: A8289P68Y2)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66800- 4094-3	88 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2022	

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph not final	part352	04/01/2022	

Labeler - Beiersdorf Inc (001177906)

Revised: 3/2023 Beiersdorf Inc