# COPPERTONE COMPLETE SUNSCREEN SPF 50- avobenzone 3%, homosalate 9%, octisalate 4.5%, octocrylene 9% 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.

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#### Coppertone Complete Lotion SPF 50

#### **Drug Facts**

#### Active ingredients

Avobenzone 3%, Homosalate 9%, Octisalate 4.5%, Octocrylene 9%

#### **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, SD alcohol 40-B, butyloctyl salicylate, diethylhexyl carbonate, glycereth-26, styrene/acrylates copolymer, butylene glycol, diisopropyl adipate, dimethicone, polyamide-8, isododecane, 1,2-hexanediol, ammonium acryloyldimethyltaurate/beheneth-25 methacrylate crosspolymer, glycerin, hydroxyacetophenone, tocopherol, ethylhexyl methoxycrylene, arachidyl alcohol, fragrance, xanthan gum, behenyl alcohol, arachidyl glucoside, disodium EDTA, sodium ascorbyl phosphate

#### Questions?

1-866-288-3330

Coppertone® Sunscreen Lotion

Complete 50

Proven UVA/UVB Protection

- + Moisturizes All Day\*
- + Feels Lightweight

Free of Oxybenzone, Octinoxate, Dyes & PABA

Water Resistant (80 Minutes)

Broad Spectrum SPF 50

Coppertone.



## COMPLETE

#### **Proven UVA/UVB Protection**

- Moisturizes All Day\*
- Feels Lightweight

Broad Spectrum UVA/UVB protection that stops up to 98% of damaging UV rays, feels lightweight - good for the whole family.

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Questions? 1-866-288-3330

\*For sun protection, use as directed.

www.coppertone.com

#### **Beiersdorf**

Beiersdorf Inc. Stamford, CT 06901 ®=reg. TM. of Beiersdorf AG,



C00021034

#### **COPPERTONE COMPLETE SUNSCREEN SPF 50**

avobenzone 3%, homosalate 9%, octisalate 4.5%, octocrylene 9% lotion

#### **Product Information**

**Product Type** HUMAN OTC DRUG Item Code (Source) NDC:66800-0030

**TOPICAL Route of Administration** 

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	3 g in 100 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 g in 100 g	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	9 g in 100 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g	

Inactive Ingredients	
Ingredient Name	Strength
ISODODECANE (UNII: A8289P68Y2)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/BEHENETH-25 METHACRYLATE CROSSPOLYMER (52000 MPA.S) (UNII: LZ291VH90H)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DOCOSANOL (UNII: 9G10E216XY)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERETH-26 (UNII: NNE56F2N14)	
ALCOHOL (UNII: 3K9958V90M)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
FRAGRANCE FRESH CITRUS FLORAL ORC1501495 (UNII: OU4GI2R2WB)	
WATER (UNII: 059QF0KO0R)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
DIETHYLHEXYL CARBONATE (UNII: YCD5000Z6L)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIMETHICONE (UNII: 92RU3N3Y10)	

Product Characteristics		
Color	white (white to off-white)	Score
Shape		Size
Flavor		Imprint Code
Contains		

# Item Code Package Description Marketing Start Date Marketing End Date  1 NDC:66800- 0030-7 207 g in 1 TUBE; Type 0: Not a Combination Product 11/02/2021	Packaging			
	# Item Code	Package Description	_	Marketing End Date
			11/02/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	11/02/2021		
	part352	11/02/2021		

### Labeler - Beiersdorf Inc (001177906)

Revised: 3/2023 Beiersdorf Inc