COPPERTONE PROTECT AND TAN SUNSCREEN SPF 45- avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion Beiersdort 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 Protect & Tan SPF 45

Drug Facts

Active ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%

Purpose

Sunscreen

Use

■ helps prevent sunburn

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.

Other information

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

Inactive ingredients

water, butyloctyl salicylate, neopentyl glycol diheptanoate, butylene glycol, styrene/acrylates copolymer, arachidyl alcohol, behenyl alcohol, dihydroxyacetone, acrylates/C12-22 alkyl methacrylate copolymer, 1,2-hexanediol, sodium stearoyl glutamate, arachidyl glucoside, erythrulose, hydroxyacetophenone, tocopherol,

fragrance, pentylene glycol, caramel

Questions?

1-866-288-3330

Coppertone® Sunscreen + Self Tanner

Glow

Protect & Tan 45

UVA/UVB Protection + Gradual Tanner

Free of Oxybenzone, Octinoxate, Dyes & PABA

Water Resistant (80 Minutes)

Broad Spectrum SPF 45

5 FL OZ (148 mL)





PROTECT & TAN

45

UVA/UVB PROTECTION
+
GRADUAL TANNER

Free of Oxybenzone, Octinoxate, Dyes & PABA

Water Resistant (80 Minutes)
Broad Spectrum SPF 45

5 FL OZ (148 mL)



How to Build a Sunkissed Glow: For best results, apply at least twice within 12 hours. Gradual color will start to appear within 12-24 hours after the first two applications. Wash your hands after application. Once your desired color is achieved, switch to a regular Coppertone sunscreen for continued sun protection. For Sunscreen Use: Follow the directions below.

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Directions ■ shake well before use ■ 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, butyloctyl salicylate, neopentyl glycol diheptanoate, butylene glycol, styrene/acrylates copolymer, arachidyl alcohol, behenyl alcohol, dihydroxyacetone, acrylates/C12-22 alkyl methacrylate copolymer, 1,2-hexanediol, sodium stearoyl glutamate, arachidyl glucoside, erythrulose, hydroxyacetophenone, tocopherol, fragrance, pentylene olycol, caramel

Questions? 1-866-288-3330

www.coppertone.com

Beiersdorf

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



COPPERTONE PROTECT AND TAN SUNSCREEN SPF 45

avobenzone 3%, homosalate 15%, octisalate 5%, octocrylene 10% lotion

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:66800-0079 Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
CARAMEL (UNII: T9D99G2B1R)	
ALLYL METHACRYLATE (UNII: G2IG50653Z)	
WATER (UNII: 059QF0KO0R)	
L-ERYTHRULOSE (UNII: WKK1W5B83O)	
DOCOSANOL (UNII: 9G10E216XY)	
DIHYDROXYACETONE (UNII: O10DDW6JOO)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
FRAGRANCE FRESH CITRUS FLORAL ORC1501495 (UNII: OU4GI2R2WB)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
TOCOPHEROL (UNII: ROZB2556P8)	

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

l	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:66800- 0079-1	148 g in 1 TUBE; Type 0: Not a Combination Product	11/03/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/03/2021	
final		,	

Revised: 2/2023 Beiersdort Inc