

**COPPERTONE LIMITED EDITION SUNSCREEN SPF 50- 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 Limited Edition 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, fragrance, arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate

Questions?

1-866-288-3330

Limited Edition

Coppertone® Sunscreen Lotion

50

Protect against damaging UVA/UVB Rays

Water Resistant (80 Minutes) Broad Spectrum SPF 50



COPPERTONE LIMITED EDITION SUNSCREEN SPF 50

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66800-4079
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
POLYESTER-7 (UNII: 0841698D2F)	
ISODODECANE (UNII: A8289P68Y2)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
FRAGRANCE FLORAL ORC0902236 (UNII: R66Z4YW3X0)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35J0OJ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DOCOSANOL (UNII: 9G1OE216XY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

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:66800-4079-8	237 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/02/2020	

Labeler - Beiersdorf Inc (001177906)