

**COPPERTONE LIMITED EDITION 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.*

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**Coppertone Limited Edition Lotion SPF 30**

***Drug Facts***

***Active ingredients***

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

***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.

***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, fragrance, arachidyl glucoside, potassium hydroxide, glyceryl stearate, PEG-100 stearate, disodium EDTA, sodium ascorbyl phosphate

### ***Questions?***

1-866-288-3330

Limited Edition

Coppertone Sunscreen Lotion

30

Protects against damaging UVA/UVB Rays

Water Resistant (80 Minutes) Broad Spectrum SPF 30

8 FL OZ (237 mL)



## **COPPERTONE LIMITED EDITION SUNSCREEN SPF 30**

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

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66800-4080
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>DISODIUM EDTA-COPPER</b> (UNII: 6V475AX06U)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (MW 500000)</b> (UNII: 5Z4DPO246A)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ006294)	
<b>POLYESTER-7</b> (UNII: 0841698D2F)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>SYNTHETIC BEESWAX</b> (UNII: 08MNR5YE2R)	
<b>FRAGRANCE FLORAL ORC0902236</b> (UNII: R66Z4YW3X0)	
<b>ARACHIDYL GLUCOSIDE</b> (UNII: 6JVV35J00J)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	

**Product Characteristics**

<b>Color</b>	white (White to Pale Yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:66800-4080-8	237 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/09/2020	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	11/09/2020		

**Labeler** - Beiersdorf Inc (001177906)

Revised: 3/2023

Beiersdorf Inc