

**COPPERTONE LIMITED EDITION SUNSCREEN SPF 50- avobenzone 3%, homosalate 10%, octisalate 5%, octocrylene 5% aerosol, spray  
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 Spray SPF 50**

***Drug Facts***

***Active ingredients***

(To Deliver) Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 5%

***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**

**Flammable:** Do not use near heat, flame, or while smoking

**Do not use** on damaged or broken skin

**When using this product**

- keep away from face to avoid breathing it
- keep out of eyes. Rinse with water to remove.
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

**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***

- shake well before each use
- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face.
- do not apply in windy conditions
- use in a well-ventilated area
- 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
- store between 20° to 25° C (68° to 77° F)
- may stain or damage some fabrics or surfaces

## ***Inactive ingredients***

SD alcohol 40-B (73.8% v/v), isobutane, neopentyl glycol dipheptanoate, polyester-27, acrylates/octylacrylamide copolymer, dimethicone, fragrance, ascorbyl palmitate

## ***Questions?***

1-866-288-3330

Limited Edition

Coppertone® Sunscreen Spray 50

Protects against damaging UVA/UVB rays

Water Resistant (80 Minutes)

Broad Spectrum SPF 50

NET WT 1.6 OZ (45 g)

**LIMITED EDITION**

**Coppertone.**  
SUNSCREEN SPRAY

**50**

Protects against damaging  
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(80 Minutes)  
Broad Spectrum  
SPF 50**

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**Drug Facts**

**Active ingredients**  
(To Deliver) Avobenzone 3%, Homosalate 10%, Octocrylene 5%

**Use** ■ helps prevent sunburn

**Warnings**  
**For external use only**  
**Flammable:** Do not use near heat, flame, or while smoking. Do not use on damaged or broken skin.  
**When using this product**  
■ keep out of eyes. Rinse with water to remove. Intentional misuse by deliberately concentrating or inhaling the product may be harmful or fatal. ■ do not puncture or incinerate. Do not store at temperatures above 120°F.  
**Stop use and ask a doctor if rash occurs**  
**Keep out of reach of children.** If product is swallowed, call a Poison Control Center right away.

**Directions** ■ shake well before use ■ apply liberally to all exposed skin ■ reapply every 2 hours or after swimming or sweating ■ immediately after toweling dry ■ **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, use 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. to 4 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 ■ store between 25°C (68° to 77°F) ■ may stain or damage soft surfaces

**Inactive ingredients** SD alcohol 40-B (73.8%), isobutane, neopentyl glycol diheptanoate, polyester-27, acrylates/octylacrylamide copolymer, dimethicone, fragrance, ascorbyl palmitate

**Questions?** 1-866-398-3333

**Beiersdorf**  
Beiersdorf, Inc., Wilton, CT 06897  
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**COPPERTONE LIMITED EDITION SUNSCREEN SPF 50**

avobenzone 3%, homosalate 10%, octisalate 5%, octocrylene 5% aerosol, spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66800-4354
<b>Route of Administration</b>	TOPICAL		



**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>FRAGRANCE FLORAL ORC0902236</b> (UNII: R66Z4YW3X0)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>POLYESTER-7</b> (UNII: 0841698D2F)	
<b>ACRYLATES CROSSPOLYMER-6</b> (UNII: 4GXD0Q3OS3)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>ISOBUTANE</b> (UNII: BXR49TP611)	

**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 Date	Marketing End Date
1	NDC:66800-4354-1	45 g in 1 CAN; Type 0: Not a Combination Product	11/04/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/04/2020	

**Labeler** - Beiersdorf Inc (001177906)