

**COPPERTONE PURE AND SIMPLE SUNSCREEN SPF 50- zinc oxide
24.08% 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.

**Coppertone Pure & Simple Spray SPF 50
Coppertone Pure & Simple Kids Spray SPF 50
Coppertone Pure & Simple Baby Sprays SPF 50**

Drug Facts

Drug Facts

Active Ingredient

Active ingredients

(To Deliver) Zinc Oxide 24.08%

Purpose

Purpose

Sunscreen

Use

Use

helps prevent sunburn

Warnings

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

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

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

Inactive ingredients isobutane, water, C12-15 alkyl benzoate, isopropyl palmitate, butyloctyl salicylate, ethylhexyl isononanoate, cetyl PEG/PPG-10/1 dimethicone, propylene glycol, cyclopentasiloxane, bis-octyldodecyl dimer dilinoleate/propanediol copolymer, dimethicone, ethylhexyl methoxycrylene, polyester-27, tea (camellia sinensis) leaf extract*, giant kelp (macrocystis pyrifera) extract*, sacred lotus (nelumbo nucifera) extract*, triethoxycaprylylsilane, beeswax, hydroxyacetophenone, PEG-12 dimethicone crosspolymer, tocopherol, 1,2-hexanediol, caprylyl glycol, caprylyl methicone, sodium chloride, cetyl dimethicone

Questions

Questions? 1-866-288-3330

Principal Display Panel

Coppertone ® Sunscreen Spray

Pure&Simple

100% Mineral Sun Protection †

Free of oxybenzone, octinoxate, PABA, parabens, dyes, fragrance

Hypoallergenic

Naturally sourced zinc oxide

With nourishing botanicals*

Water Resistant (80 minutes)

Broad Spectrum SPF 50

NET WT 5 OZ (142 g)

Pure & Simple offers 100% mineral sun protection†
and is free of parabens, fragrances, dyes, & oxybenzone.



Pure & Simple

100% Mineral Sun Protection†

50

FREE OF oxybenzone, octinoxate, PABA, parabens, dyes, fragrance

- Hypoallergenic
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WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 50

NET WT 5 OZ (142 g)

Drug Facts	
Active ingredient (To Deliver) Zinc Oxide 24.08%	Purpose Sunscreen
Use ■ helps prevent sunburn	
Warnings	
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Do not use on damaged or broken skin	
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<p>DOT-2P-M5706</p>	
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*Botanical extracts †Based on zinc oxide active

Beiersdorf

Beiersdorf Inc. Wilton, CT 06897
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20006388

#1
PEDIATRICIAN
RECOMMENDED
BRAND

Coppertone[®]
SUNSCREEN SPRAY

Pure & Simple
kids[®]

100% Mineral
Sun Protection†

50

FREE OF oxybenzone, octinoxate,
PABA, parabens, dyes, fragrance

- 🌿 Hypoallergenic
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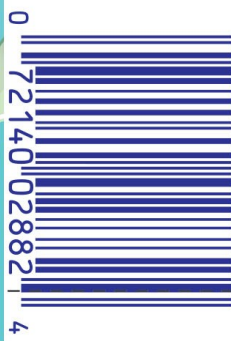
WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 50

NET WT 5 OZ (142 g)

Pure & Simple offers 100% mineral sun protection†
and is free of parabens, fragrances, dyes, & oxybenzone.

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Active ingredient (To Deliver) Zinc Oxide 24.08%	Sunscreen
Use ■ helps prevent sunburn	
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Pure & Simple offers 100% mineral sun protection[†] and is free of parabens, fragrances, dyes, & oxybenzone.



Coppertone[®]
SUNSCREEN SPRAY



100% Mineral Sun Protection[†]

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BROAD SPECTRUM SPF 50

NET WT 5 OZ (142 g)

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DOT-2P-M5706



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COPPERTONE PURE AND SIMPLE SUNSCREEN SPF 50

zinc oxide 24.08% aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66800-4744
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	240.8 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
POLYESTER-7 (UNII: 0841698D2F)	
ISOBUTANE (UNII: BXR49TP611)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
BIS-OCTYLDODECYL DIMER DILINOLEATE/PROPANEDIOL COPOLYMER (UNII: TY3J98ZR7R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
NELUMBO NUCIFERA LEAF (UNII: 60C608DPVT)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
TOCOPHEROL (UNII: ROZB2556P8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66800-4744-5	142 g in 1 CAN; Type 0: Not a Combination Product	01/01/2021	
2	NDC:66800-4744-6	142 g in 1 CAN; Type 0: Not a Combination Product	01/01/2021	
3	NDC:66800-4744-7	142 g in 1 CAN; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2021	

