

**COPPERTONE PURE AND SIMPLE SUNSCREEN SPF 50- zinc oxide
24.08% 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 Pure & Simple Lotion SPF 50

Drug Facts

Active ingredients

Zinc Oxide 24.08%

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

■ shake well before each 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

Questions?

1-866-288-3330

Coppertone® Sunscreen Lotion

Pure & Simple

100% Mineral Sun Protection †

50

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

- Hypoallergenic
- Naturally sourced zinc oxide
- With nourishing botanicals*

Water Resistant (80 Minutes)

Broad Spectrum SPF 50

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

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

Questions? 1-866-288-3330

*Botanical extracts
 †Based on zinc oxide active

Beiersdorf
 Beiersdorf Inc., Wilton, CT 06097
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#1
PEDIATRICIAN RECOMMENDED
 BRAND

Coppertone
 SUNSCREEN LOTION

Pure & Simple
kids.

100% Mineral Sun Protection*

50

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WATER RESISTANT (80 MINUTES)
 BROAD SPECTRUM SPF 50

6 FL OZ (177 mL)

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

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COPPERTONE PURE AND SIMPLE SUNSCREEN SPF 50

zinc oxide 24.08% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66800-3993
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24.08 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8TOX)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
TEA LEAF (UNII: GH42T47V24)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYESTER-7 (UNII: 0841698D2F)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BIS-OCTYLDODECYL DIMER DILINOLEATE/PROPANEDIOL COPOLYMER (UNII: TY3J98ZR7R)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
MACROCYSTIS PYRIFERA (UNII: K31S30G5C4)	
NELUMBO NUCIFERA LEAF (UNII: 60C608DPVT)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)	
TOCOPHEROL (UNII: ROZB2556P8)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

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:66800-3993-2	59 g in 1 TUBE; Type 0: Not a Combination Product	11/03/2020	
2	NDC:66800-3993-6	177 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/03/2020	
3	NDC:66800-3993-7	177 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/03/2020	
4	NDC:66800-3993-1	59 g in 1 TUBE; Type 0: Not a Combination Product	11/03/2020	
5	NDC:66800-3993-5	177 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/03/2020	

Labeler - Beiersdorf Inc (001177906)

Revised: 3/2023

Beiersdorf Inc