COPPERTONE PURE AND SIMPLE SPF 50- zinc oxide lotion
Bayer HealthCare LLC.

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 UI 1613993

Drug Facts

Active ingredients

Zinc Oxide 24.08%

Purpose

Sunscreen

Uses

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

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

Other information

■ protect this product from excessive heat and direct sun

■ may stain or damage some fabrics or surfaces

Inactive ingredients 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*, triethoxycaprylysilane, beeswax, hydroxyacetophenone, PEG-12 dimethicone crosspolymer, tocopherol, 1,2-hexanediol, caprylyl glycol, sodium chloride

Questions? 1-866-288-3330

New
Coppertone®
SUNSCREEN LOTION
Pure &
Simple
+ 100% natural botanicals*
Tear Free
Hypoallergenic & Gentle 50
Zinc Oxide Protection
No PABA, Parabens, Phthalates,
Fragrances, Dyes, Oxybenzone
Water Resistant (80 Minutes)
Broad Spectrum SPF 50
6 FL OZ (177 mL)

COPPERTONE PURE AND SIMPLE SPF 50

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-7458
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	250.19 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
NELUMBO NUCIFERA LEAF (UNII: 60C608DPVT)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BIS-OCTYLDODECYL DIMER DILINOLEATE/PROPANEDIOL COPOLYMER (UNII: TY3J98ZR7R)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Product Characteristics

Color	yellow (Off-white to light yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-7458-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2018	09/01/2021

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2018	09/01/2021

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 12/2019 Bayer HealthCare LLC.