COPPERTONE KIDS SPF 70 PLUS- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone 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 Kids SPF 70 Lotion UI 1612464

Drug Facts

Active ingredients

Avobenzone 3%, Homosalate 13%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6%

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

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, Butyloctyl Salicylate, Butylene Glycol, Styrene/Acrylates Copolymer, Bis-Stearyl Ethylenediamine/Neopentyl Glycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer, Benzyl Alcohol, Tocopherol (Vitamin E), Diethylhexyl Syringylidenemalonate, Retinyl Palmitate (Vitamin A Palmitate), Sodium Ascorbyl Phosphate, Triethanolamine, Chlorphenesin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Oleth-3, Fragrance, Disodium EDTA.

Questions?

866-288-3330

Distributed by

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Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

New Look

Coppertone ®
SUNSCREEN LOTION

kids

Stays on

Strong When

Kids Play 70

Water Resistant
(80 minutes)

Broad Spectrum

SPF 70

#1 PEDIATRICIAN
RECOMMENDED BRAND

8 FL OZ (237 mL)

COPPERTONE KIDS SPF 70 PLUS

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-7281
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.9 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	133.9 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	103 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	61.8 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
TROLAMINE (UNII: 9O3K93S3TK)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics			
Color	white (White to yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-7281-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/21/1999	11/01/2017
2	NDC:11523-7281-2	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/01/2017	08/01/2020

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/21/1999	05/01/2021

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 7/2019 Bayer HealthCare LLC.