TOPCARE EVERYDAY KIDS MINERAL SUNSCREEN- zinc oxide lotion TOPCO ASSOCIATES 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.

TopCare Everyday Kids Mineral Sunscreen Lotion

Active ingredients

Zinc Oxide 21.6%

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 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
- children under 6 months of age: Ask a doctor
- 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-sleeved shirts, pants, hats, and sunglasses

Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive ingredients

water, C12-15 alkyl benzoate, caprylic/capric triglyceride, styrene/acrylates copolymer, octyldodecyl citrate crosspolymer, phenyl trimethicone, cetyl PEG/PPG-10/1 dimethicone, dimethicone, polyhydroxystearic acid, glycerin, ethyl methicone, cetyl dimethicone, silica, colloidal oatmeal, chrysanthemum parthenium (feverfew) flower/leaf/stem juice, glyceryl behenate, phenethyl alcohol, caprylyl glycol, bis-divinyl dimethicone PEG-10 dimethicone crosspolymer, sodium chloride, phenoxyethanol, chlorphenesin



TopCare Kids Mineral Sunscreen Lotion SPF 50 provides a physical layer of worry-free broad-spectrum protection from the sun, Ideal for kids' sensitive skin, this easy-on, mineral based sunscreen lotion is lightweight and dries clearly and quickly to keep you on the move.

Drug Facts Active ingredients Purpose Zinc Oxide 21,6% __

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Questions or comments? Call toll free 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 © TOPCO FOEA0820 QUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com





Scan here for more information or call 1-888-423-0139



†Formula is compliant with HI SB2571,

*No parabens separately added to preserve this product,

TOPCARE EVERYDAY KIDS MINERAL SUNSCREEN

zinc oxide lotion

Product Information

HUMAN OTC DRUG Item Code (Source) **Product Type** NDC:36800-257

Route of Administration

TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	216 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M)			
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)			
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
GLYCERIN (UNII: PDC6A3C0OX)			
ETHYL METHICONE (8 MPA.S) (UNII: 3YWG8XYT8H)			
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
OATMEAL (UNII: 8PI54V663Y)			
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)			
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
CHLORPHENESIN (UNII: 1670DAL4SZ)			
TANACETUM PARTHENIUM FLOWER (UNII: 7TVV9D7I89)			

Packaging					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:36800-257- 09	89 mL in 1 TUBE; Type 0: Not a Combination Product	12/02/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part352	12/02/2020			

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 4/2022 TOPCO ASSOCIATES LLC