TOPCO TOPCARE EVERYDAY BABY PROTECTION SUN SPF 50- octisalate, 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.

TOPCO TOPCARE EVERYDAY BABY PROTECTION SUN LOTION SPF 50

Active ingredients

Octisalate 5.0%, Zinc Oxide 14.5%

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 casued 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, Neopentyl Glycol Diheptanoate, Propylene Glycol, Tridecyl Salicylate, Cyclopentasiloxane, Cetyl PEG/PPG-10/1 Dimethicone, PEG-12 Dimethicone Crosspolymer, Triethoxycaprylylsilane, Aloe Barbadensis Leaf Juice, Ethylhexyl Palmitate, Caprylyl Glycol, Phexoethanol, Hexylene Glycol, Sodium Chloride.

Label

TOPCO TOPCARE EVERYDAY BABY PROTECTION SUN SPF 50

octisalate, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-347
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	145 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SORBIC ACID (UNII: X045WJ989B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-347-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/02/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	11/02/2018	

Labeler - TOPCO ASSOCIATES LLC (006935977)

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