TOPCARE EVERYDAY ULTRA PROTECTION SPF 50- avobenzone, homosalate, octisalate, octocrylene 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 ULTRA PROTECTION SUN LOTION SPF 50

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 4.5%, Octocrylene 8.0%

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, polyester-7, neopentyl glycol diheptanoate, glycerin, styrene/acrylates copolymer, aluminum starch octenylsuccinate, silica, phenoxyethanol, isododecane, arachidyl alcohol, beeswax, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, behenyl alcohol, tocopherol (vitamin E), arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate, fragrance

Label

TOPCARE EVERYDAY ULTRA PROTECTION SUN LOTION SPF 50 8.0 FL OZ (237mL)

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Avobenzone 3.0% Homosalate 10.0% Octisatate 4.5% Octocrylene 8.0%	Sunscreen
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Inactive ingredients water, polyester-7, neopentyl gly starch octeny/succinate, styrene/acrylates copolymer, silica, phe	
alcohol, beeswax, ethylhexylglycerin, acrylates/C10-30 alkyl acry	late crosspolymer, behenyl alcoho
tocopherol (vitamin E), arachidyl glucoside, glyceryl stearate, PEG	-100 stearate, potassium hydroxide
disodium EDTA, sodium ascorbyl phosphate, fragrance	
ISTRIBUTED BY TOPCO ASSOCIATES	LLC
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This Top Care® product is laborato	
This Top Care® product is laborato tested to guarantee its highest qu Your total satisfaction is guarantee	ality. 00
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*No parabens separately added to preserve this product

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DERMATOLOGIST TESTED

WATER RESISTANT (80 MINUTES)

8 FL OZ (237 mL)

TOPCARE EVERYDAY ULTRA PROTECTION SPF 50 avobenzone, homosalate, octisalate, octocrylene lotion							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code	tem Code (Source)		NDC:36800-132		
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingred	dient Name		Basis of Stren	gth	Strength		
AVOBENZONE (UNII: G63QQF2NO	X) (AVOBENZONE - UNII:G6	3QQF2NOX)	AVOBENZ ONE		30 mg in 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06	5V4M95S)	HOMOSALATE		100 mg in 1 mL		
OCTISALATE (UNII: 4X49Y0596W)	(OCTISALATE - UNII:4X49Y0	596W)	OCTISALATE		45 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6V	M) (OCTOCRYLENE - UNII:5	A68WGF6WM)	OCTOCRYLENE		80 mg in 1 mL		
					-		

	Ingredient Name		Strengt
WATER (UNII: 059QF0	-		
POLYESTER-7 (UNII:	0841698D2F)		
NEOPENTYL GLYCO	L DIHEPTANOATE (UNII: 5LKW3C543X)		
GLYCERIN (UNII: PDC	6A3C0OX)		
ALUMINUM STARCH	OCTENYLSUCCINATE (UNII: I9PJ006294)		
SILICON DIOXIDE (U	NII: ETJ7Z6XBU4)		
PHENOXYETHANOL	(UNII: HIE492ZZ3T)		
SODODECANE (UNII	: A8289P68Y2)		
ARACHIDYL ALCOHO	DL (UNII: 1QR1QRA9BU)		
WHITE WAX (UNII: 70	G1J5DA97F)		
ETHYLHEXYLGLYCE	RIN (UNII: 147D247K3P)		
BUTYL METHACRYL (UNII: V5RS026Q0H)	ATE/METHYL METHACRYLATE/METHACRYLIC	ACID/STYRENE CROSSI	POLYMER
DOCOSANOL (UNII: 9	9G10E216XY)		
ALPHATOCOPHER	OL, DL- (UNII: 7QWA1RIO01)		
ARACHIDYL GLUCOS	SIDE (UNII: 6JVW35JOOJ)		
GLYCERYL STEARAT	E/PEG-100 STEARATE (UNII: RD25J5V947)		
POTASSIUM HYDRO	XIDE (UNII: WZH3C48M4T)		
EDETATE DISODIUM	I (UNII: 7FLD91C86K)		
SODIUM ASCORBYL	PHOSPHATE (UNII: 836SJG51DR)		
	MER TYPE A (ALLYL PENTAERYTHRITOL CRO	OSSLINKED) (UNII: 71DD5	V995L)
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
	37 mL in 1 BOTTLE; Type 0: Not a Combination roduct	02/11/2014	
	oformation		
Marketing In			
Marketing II Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 6/2021

TOPCO ASSOCIATES LLC