

TOPCARE EVERYDAY SPORT SUN SPF 50- avobenzone, homosalate, 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 Sport Sun Lotion SPF 50

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octocrylene 6.0%

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 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, cetearyl alcohol, stearyl alcohol, glycerin, acrylates/C12-22 alkyl methacrylate copolymer, cetyl alcohol, carbomer, ceteth-10 phosphate, dicetyl phosphate, coco-glucoside, xanthan gum, disodium EDTA, methyl dihydroabietate, lauryl PEG-8 dimethicone, phenylisopropyl dimethicone, polyglyceryl-3 stearate/isostearate/dimer dilinoleate crosspolymer, sodium ascorbyl phosphate, tocopheryl acetate, aloe barbadensis leaf juice, phenoxyethanol, triethanolamine, propylene glycol, hydroxyacetophenone

Label



TOPCARE EVERYDAY SPORT SUN SPF 50

avobenzone, homosalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-261
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
COCO GLUCOSIDE (UNII: ICS790225B)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-261-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/28/2020	

Labeler - TOPCO ASSOCIATES LLC (006935977)

