

SEA STARWORT SOOTHING SUNSCREEN SPF 35- titanium dioxide lotion
CU LIFESTYLE 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.

Sea Starwort Soothing Sunscreen SPF 35

30 ml 1.0 fl. oz.

Drug Facts

Active Ingredients

Titanium Dioxide 9.7 %

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
- Apply to all skin exposed to the sun
- Reapply at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating
- 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

Ingredients

Aqua, Pyrus malus (apple) fruit water*, Titanium Dioxide, Caprylic /Capric Triglyceride, C10-18 Triglycerides, Glycerin, Dicaprylyl Ether, Simmondsia Chinensis (Jojoba) Seed Oil*, Silica, Polyglyceryl-6 Polyhydroxystearate, Polyglyceryl-6 Polyricinoleate, Jojoba esters, Magnesium Sulfate, Sodium Chloride, Glyceryl Caprylate, Polyhydroxystearic Acid, Glyceryl Undecylenate, Xanthan Gum, Tocopherol, Bisabolol, Aster Maritima/Tripolium Extract, Chamomilla Recutita (Matricaria) Flower Extract*

SEA STARWORT SOOTHING SUNSCREEN SPF 35

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75391-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.91 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
XANTHAN GUM (UNII: TTV12P4NEE)	
APPLE FRUIT OIL (UNII: 9NT987I3A8)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75391-002-30	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/15/2020	

Labeler - CU LIFESTYLE LLC (010080461)

Revised: 4/2020

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