

CENTELLA CALMING SUNSCREEN- centella calming sunscreen cream
GUANGZHOU YUSONG FINE CHEMICALS Co., Ltd

84558-007

Active Ingredient(s)

Zinc Oxide 2.85%
Titanium Dioxide 2.76%
Ethylhexyl Salicylate 5%
Phenylbenzimidazole Sulfonic Acid 3.2%

Purpose

Sunscreen

Use

- 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

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.
- Children under 6 months of age : Ask a doctor.
- Reapply at least every 2 hours, and after 40 minutes of swimming or sweating.
- 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 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-sleeve shirts, pants, hats, and sunglasses

Other information

- Protect the product in this container from excessive heat and direct sun.
- Sun alert : Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

Aqua, Glycerin, Silica, Butylene Glycol, Neopenty| Gly-col Diheptanoate, Cyclopentasiloxane, Isohexadecane, Cetyl| Peg/Ppg-10/1 Dimethicone, C12-15 Alkyl Benzo-ate, Cyclohexasiloxane, Niacinamide, Magnesium Sul-fate, Distearidimonium Hectorite, Madecassoside,1,2-Hexanediol, Peg-10 Dimethicone, Sorbitan Sesqui-oleate, Hydroxyacetophenone, Sodium Hydroxide,

Package Label - Principal Display Panel



CENTELLA CALMING SUNSCREEN			
centella calming sunscreen cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84558-007
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.76 g in 100 mL
ETHYLHEXYL SALICYLATE (UNII: 4X49Y0596W) (ETHYLHEXYL SALICYLATE - UNII:4X49Y0596W)	ETHYLHEXYL SALICYLATE	5 g in 100 mL
PHENYLBENZIMIDAZOLE SULFONIC ACID (UNII: 9YQ9DI1W42) (PHENYLBENZIMIDAZOLE SULFONIC ACID - UNII:9YQ9DI1W42)	PHENYLBENZIMIDAZOLE SULFONIC ACID	3.2 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2.85 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
PROPANEDIOL (UNII: 5965N8W85T)	
PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER (UNII: 788QAG3W8A)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYALURONATE (UNII: YSE9PPT4TH)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
SODIUM S-(2-HYDROXY-3-(3-(TRIHYDROXYSILYL)PROPOXY)PROPYL) SULFUROTHIOATE (UNII: 2V56GQW1BM)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LACTIC ACID (UNII: 33X04XA5AT)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	
HYDROLYZED CASEIN (ENZYMATIC; 1000 MW) (UNII: M93H91U80R)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
HYALURONIC ACID (UNII: S270N0TRQY)	
AQUA (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICA (UNII: ETJ7Z6XBU4)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
NIACINAMIDE (UNII: 25X51I8RD4)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
MADECASSOSIDE (UNII: CQ2F5O6YIY)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PEG-10 DIMETHICONE (200 CST) (UNII: 287GF3Y3WC)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84558-007-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/10/2025	

Labeler - GUANGZHOU YUSONG FINE CHEMICALS Co., Ltd (545488483)

Establishment

Name	Address	ID/FEI	Business Operations
GUANGZHOU YUSONG FINE CHEMICALS Co., Ltd		545488483	manufacture(84558-007)

Revised: 2/2025

GUANGZHOU YUSONG FINE CHEMICALS Co., Ltd