

ECO BARRIER NON CHEMICAL SUN- zinc oxide, titanium dioxide cream
JEIL H&B INC.

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.

ACTIVE INGREDIENT

Active ingredients: Zinc Oxide 10%, Titanium Dioxide 8%

INACTIVE INGREDIENT

Inactive ingredients: Water, Cyclomethicone, Propanediol, Dicaprylyl Carbonate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Cetyl Ethylhexanoate, Aluminum Hydroxide, 1,2-Hexanediol, Disteardimonium Hectorite, Hydrogen Dimethicone, Magnesium Sulfate, Salvia Hispanica Seed Extract, Stearic Acid, Centella Asiatica Extract, Houttuynia Cordata Extract, Polyglyceryl-2 Dipolyhydroxystearate, Dimethicone Crosspolymer, Phenyl Trimethicone, Lavandula Angustifolia (Lavender) Oil, Fructooligosaccharides, Saccharide Hydrolysate, Pullulan, Water, Ethylhexylglycerin, Octyldodecanol, Hydrogenated Lecithin, Echium Plantagineum Seed Oil, Cetearyl Alcohol, Helianthus Annuus (Sunflower) Seed Oil, Butylene Glycol, Caprylyl Glycol, Cardiospermum Halicacabum Flower/Leaf/Vine Extract, Sorbitan Sesquioleate, Cholesterol, Phytosphingosine, Ceramide EOP, Ceramide NS, Ceramide NP, Ceramide AP, Helianthus Annuus (Sunflower) Seed Oil Unsaponifiables, Chamomilla Recutita (Matricaria) Flower Oil, Tocopherol, Hyaluronic Acid, Hydrolyzed Hyaluronic Acid, Sodium Hyaluronate

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings: For external use only. Avoid contact with eyes. Discontinue use if signs of irritation or rashes appear. Keep out of reach of children.

DESCRIPTION

Uses: Hypoallergenic sun cream for children and easily irritated sensitive skin. The natural 100% mineral filter forms a physical barrier to reflect UV light from the surface of the skin. With a skin-friendly moisturizing formula, this sun cream smoothes into the skin easily and protects the skin from external stimuli like fine dust. This mild sun cream is suitable for all skin types, decreases the risk of skin cancer and early skin aging caused by the sun.

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

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

Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)

Titanium Dioxide

4.0 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Propanediol (UNII: 5965N8W85T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71982-010-02	1 in 1 CARTON	12/01/2017	
1	NDC:71982-010-01	50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2017	

Labeler - JEIL H&B INC. (694788123)

Registrant - JEIL H&B INC. (694788123)

Establishment

Name	Address	ID/FEI	Business Operations
COSON Co., Ltd._Osan Plant		689847210	manufacture(71982-010)

Revised: 1/2018

JEIL H&B INC.