

EARTHS BEST MINERAL SUNSCREEN BROAD SPECTRUM SPF30 - zinc oxide, titanium dioxide lotion

The Hain Celestial Group, 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.

Drug Facts

Zinc Oxide 14.5%

Titanium Dioxide 2.0%

Sunscreen

- Helps prevent sunburns
- If used as described with other sun protection measures, decreases the risk of skin cancer and early skin aging, caused by the sun.

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 skin rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Apply liberally 15 minutes before sun exposure. Reapply after 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours. Children under 6 months, ask a doctor . **Skin Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with Broad Spectrum SPF 15 or higher and other protective measures including: limit time in the sun, especially from 10am to 2pm and wear long-sleeved shirts, pants, hats and sunglasses.

Aqua (Water), Aloe Barbadensis Leaf Juice (1), Caprylic/Capric Triglycerides, Dimethicone, Ethylhexyl Palmitate, Sorbitan Sesquioleate, Glycerin, Butyrospermum Parkii (Shea Butter), Helianthus Annuus (Sunflower) Seed Oil (1), Simmondsia Chinensis (Jojoba) Seed Oil (1), Polyglyceryl-3 Ricinoleate, Vitis Vinifera (Grape) Seed Oil, Calendula Officinalis Flower Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Magnesium Sulfate, Silica, Sodium Chloride, Tocopheryl Acetate, Benzyl Alcohol, Phenoxyethanol, Polyhydroxystearic Acid.

(1) Certified Organic Ingredients

Questions? Call (877) 527-6801 or visit www.earthsbest.com



Drug Facts

Active Ingredient	Purpose
Zinc Oxide 14.0%	Sunscreen
Titanium Dioxide 2.0%	Sunscreen

Uses • Helps prevent sunburn • If used as directed with other sun protection measures (see Warnings), 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. Stop use and refer to a doctor if skin 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 40 minutes of swimming or sweating, immediately after towel drying, and at least every 2 hours. Children under 6 months: ask a doctor. Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with broad spectrum SPF 15 or higher and other protective measures including: Wear a hat in sun, especially hats that shade face, neck and shoulders.

Other Ingredients Aqua (Water), Aloe Barbadensis Leaf Juice¹, Caprylic/Triglyceride, Dimethylsiloxane, Ethylhexyl Stearate, Sorbitol Caprylate, Glyceryl Stearate, Tocopherol, Helianthus Annuus (Sunflower) Seed Oil², Dimethylsiloxane (Liquid), Zinc Oxide, Polypropylene Glycol-15-Dimethyl Silylate, Zinc Oxide, Carbocysteine, Pantothenol, Ethylhexyl Stearate, Ethylhexyl Stearate, Tocopherol Acetate, Benzyl Alcohol, Phenoxyethanol, Hydroxyethylcellulose, Potassium Sorbate, Potassium Sorbate.

Other Information Protect this product from excessive heat and direct sun.

Questions? Visit www.earthsbest.com or call 877-827-4801

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 LAB00700A002



zinc oxide, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-0212
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.5 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
JOJOBA OIL (UNII: 724GKU717M)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
SHEA BUTTER (UNII: K49155WL9Y)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CHAMOMILE (UNII: FGL3685T2X)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-0212-4	113 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/19/2011	

Labeler - The Hain Celestial Group, Inc. (858894996)

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		858894996	manufacture

Revised: 5/2012

The Hain Celestial Group, Inc.