AV3712501 MINERAL SUNSCREEN SPF 18 - titanium dioxide cream 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

ACTIVE INGREDIENT

Titanium Dioxide 7.0%

USAGE

- Helps prevent sunburn
- Apply liberally at least 20 minutes prior to sun exposure
- Reapply as needed
- For children under the age of 6 months please contact physician before use

WARNINGS and PRECAUTIONS

For external use only.

When using this product avoid contact with eyes. If contact occurs, rinse throughly with water to remove.

Stop use and consult a physician if rash or irritation develops and lasts.

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

QUESTIONS?

1-800-227-5120 or www.AvalonOrganics.com



Drug Facts

Active ingredient

Purpose

Titanium dioxide 7.0% Natural Mineral Sunscreen

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Directions - Apply liberally at least 20 minutes prior to sun exposure.

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Other Information

For lot number and expiration see base of container

Inactive ingredients Purified water, octyl palmitate (palm Inactive ingredients: Purhele water, octyl palmitate (pain emollient), castor oil phosphate, triethovycaprylysilane (emulsifer), glyceryl stearate (vegetable emollient), celearyl alcohol (coconut emollient), evejetable glycerin, phenocyethanio (natural preservative), benzyl alcohol and potassium sorbate (natural preservative) serzivi alcohol and potassium sorbate (natural preservative system), vitamin E, steanic acid (regetable emollient), organic alce betradensis leaf juice, organic sunflower and igioba seed dils, organic green tea leaf, chamomile flower, calendula flower and ginkgo biloba leaf extracts, vitamin BS, allantoin (comfrey root conditioner), cat kernel flour, organic achiarace leaf and varrow extracts, polysorbate 60 flour, organic echinacea leaf and yarrow extracts, polysorbate 60 (emulisfier), potassium cetyl phosphate (vegetable emulsifier), cetyl phosphate (vegetable emulsifer) and xanthan gum.

Questions? 1-800-227-5120 or www.AvalonOrganics.com

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AV3712501 MINERAL SUNSCREEN SPF 18

titanium dioxide cream

Product Information

Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:61995-1125

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP) Titanium Dioxide 7.0 g in 100 g

Packaging Item Code Package Description **Marketing Start Date Marketing End Date** 1 NDC:61995-1125-3 99 g in 1 BOTTLE

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2006	

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

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

Revised: 3/2011 The Hain Celestial Group, Inc.