

DESERT ESSENCE MINERAL SUNSCREEN SPF 35- zinc oxide cream
Autumn Harp, 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.

Desert Essence Mineral Sunscreen SPF 35

Active Ingredient

Zinc Oxide (15%)

☐ 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

Do not use on damaged or broken skin.

When using this product

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

Stop use and ask a doctor if rash occurs.

Keep out of reach of children

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

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply 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 Broad Spectrum SPF 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

- children under 6 months: ask a doctor

Other information

- protect this product container from excessive heat and direct sun

Inactive ingredients

Ethyl Palmate, Aloe Barbadosis Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Sorbitan Olivete, Butyrospermum Parkii (Shea Butter), Beeswax (Cera Alba), Anthemis Nobilis Flower Oil (Chamomile), Punica Granatum Extract (Pomegranate), Punica Granatum Fruit Juice (Pomegranate), Tocopherol (Vitamin E), Glycerin (Palm), Gluconolactone, Sodium Benzoate, Maltodextrin, Silica.

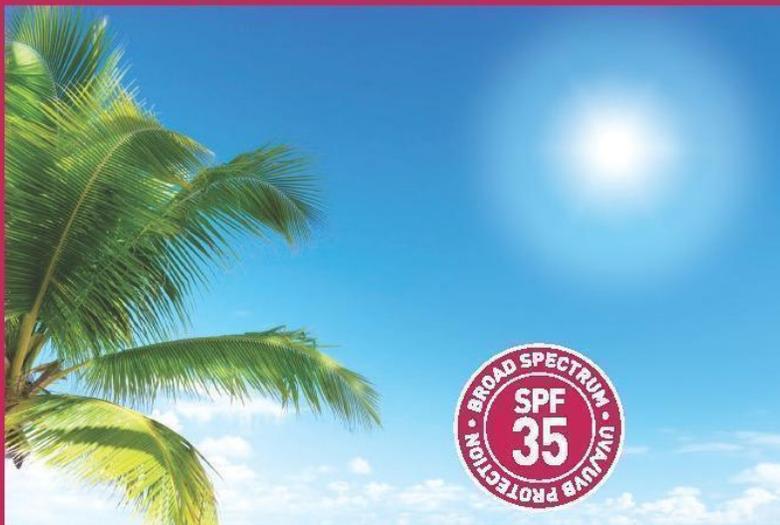
Principal Display Panel

image components

100% Vegetarian / Wheat & Gluten Free. NO: Parabens, Sodium Lauryl/Laureth Sulfates, phthalates, artificial fragrances or colors, EDTA, glycol or petroleum-based ingredients. Cruelty Free and Biodegradable Formula: No animal testing of raw materials or finished product. No Phosphates.

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Inactive Ingredients	
Ethyl Palmate*, Aloe Barbadosis Leaf Juice*, Helianthus Annuus (Sunflower) Seed Oil*, Sorbitan Olivete (Olive), Butyrospermum Parkii (Shea) Butter*, Beeswax (Cera Alba)*, Anthemis Nobilis Flower Oil (Chamomile), Punica Granatum Extract (Pomegranate)*, Punica Granatum Fruit Juice (Pomegranate), Tocopherol (Vitamin E), Glycerin (Palm), Gluconolactone, Sodium Benzoate, Maltodextrin, Silica. * Certified Organic	

DESERT
ESSENCE[®]
ORGANICS





MINERAL SUNSCREEN
DAILY FACE PROTECTION
with Shea Butter, Aloe Vera,
and Pomegranate
Non-Nano
3 fl. oz. (88.7 mL)



Color variations in product may occur due to natural ingredients. Item No.: 3783NDE
Distributed by Desert Essence
Hempstead, NY 11790
www.desertessence.com
MADE IN THE U.S.A.
Certified to NSF/ANSI 306 by QAI
www.QAI-INC.com







DESERT ESSENCE MINERAL SUNSCREEN SPF 35

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0236
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (zinc oxide - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE (UNII: V5VD430YW9)	
CALCIUM GLUCONATE (UNII: SQE6VB453K)	
POMEGRANATE JUICE (UNII: 99S671U9KB)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SOYBEAN OIL (UNII: 241ATL177A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
POMEGRANATE (UNII: 56687D1Z4D)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
ETHYL PALMITATE (UNII: IRD3M534ZM)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
ETHYL LINOLEATE (UNII: MJ2YTT4J8M)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0236-1	88.7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/15/2013	

Labeler - Autumn Harp, Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0236)

Revised: 7/2013

Autumn Harp, Inc.