

DR. MERCOLA SUNSCREEN BROAD SPECTRUM SPF-15- zinc oxide cream
Pure Source, LLC

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.

DR. MERCOLA Sunscreen Broad Spectrum SPF-15

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Active Ingredient

Zinc Oxide (9.5%)

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), sunscreen 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. Rinse with water to remove.

Stop use and ask a doctor

if rash occurs

Keep out of reach of children.

If product is 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.
- **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 value 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
- Re-apply:

- After 40 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours

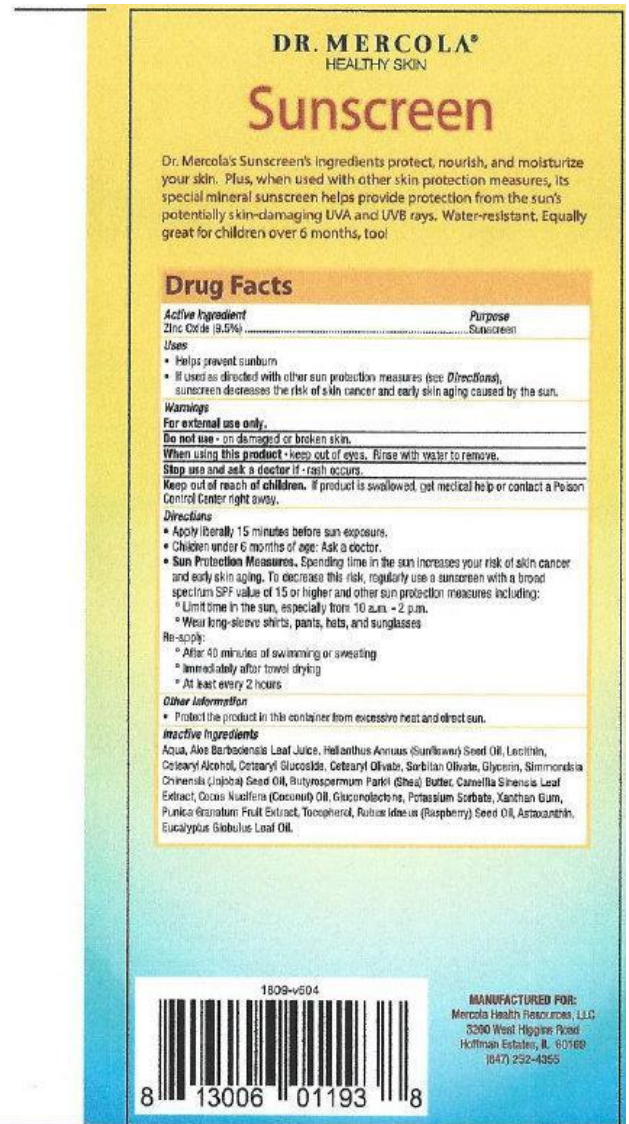
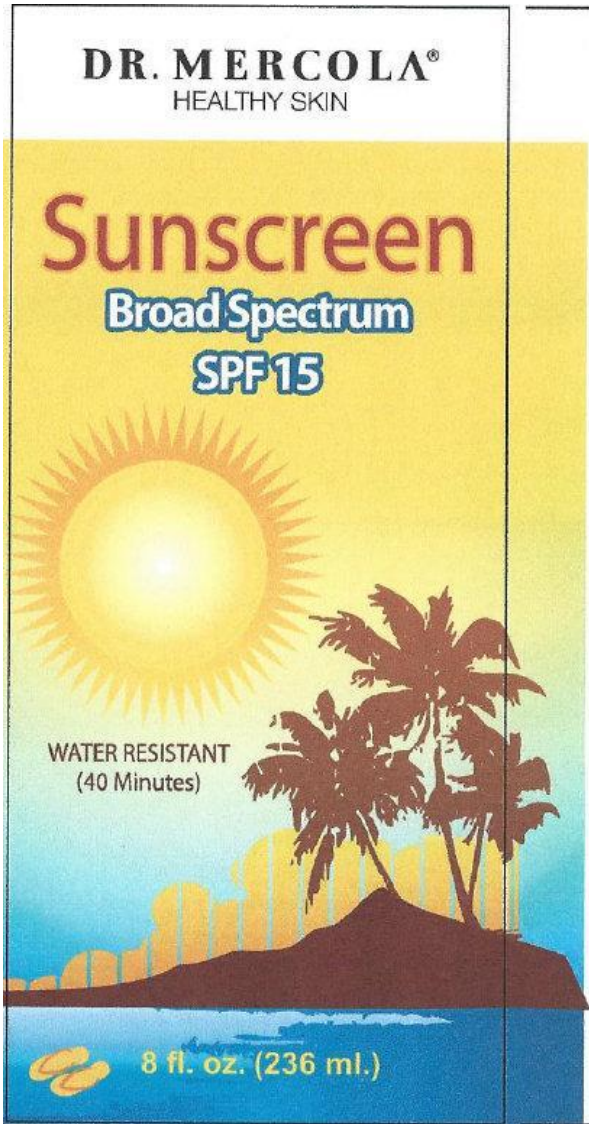
Other Information

- Protect the product in this container from excessive heat and direct sun

Inactive Ingredients

Aqua, Aloe Barbadensis Leaf Juice, Helianthus Annuus (Sunflower) Seed Oil, Lecithin, Cetearyl Alcohol, Cetearyl Glucoside, Cetearyl Oliviate, Sorbitan Oliviate, Glycerin, Simmonds Chinensia (Jojoba) Seed Oil, Butyrospermum ParkII (Shea) Butter, Camellia Sinensis Leaf Extract, Cocos Nucifera (Coconut) Oil, Glucuro lactone, Potassium Sorbate, Xanthan Gum, Punica Granalum Fruit Extract, Tocopherol, Rubus Idaeus (Raspberry) Seed Oil, Astaxanthin Eucalyptus Globulus Leaf Oil.

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zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65121-884
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	95 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
GLYCERIN (UNII: PDC6A3C0OX)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COCONUT OIL (UNII: Q9L0O73W7L)	
GLUCUROLACTONE (UNII: XE4Y3016M9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POMEGRANATE (UNII: 56687D1Z4D)	
TOCOPHEROL (UNII: R0ZB2556P8)	
RASPBERRY SEED OIL (UNII: 9S8867952A)	
ASTAXANTHIN (UNII: 8XPW32PR7I)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65121-884-15	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/28/2014	

Labeler - Pure Source, LLC (080354456)**Establishment**

Name	Address	ID/FEI	Business Operations
Pure Source, LLC		080354456	manufacture(65121-884)

Revised: 2/2017

Pure Source, LLC