

HAPPY FARM BOTANICALS PROTECTIVE DAY CREAM SPF 30- zinc oxide, titanium dioxide cream

Happy Farm Botanicals, 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.

Sunscreen Product Listing

Active Ingredients Section

Active Ingredients

Non-Nano Uncoated Zinc Oxide, 2.34%

Titanium Dioxide, 3.60%

Purpose

Sunscreen

Uses

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

Warnings

For external use only

Do not use on damage or broken skin.

Do Not Use

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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 product is swallowed get medical help or contact a poison control center right away.

Directions

- **Shake well**
- Apply liberally 15 minutes before sun exposure
- **Reapply:**
- After 40 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 of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10:00 am – 2:00 pm.\
- Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor

Other Information

Other Information

- Protect this product from excessive heat and direct sun.


Inactive Ingredients

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Water, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Caprylic/Capric Triglycerides, Pentylene Glycol, Sorbitan Oleate Decylglucoside Crosspolymer, Glycerin, Ethyl Lauroyl Arginate HCl, VP/Eicosene Copolymer, Glyceryl Stearate.

Principal Display Panel Front of Package

Produced by Happy Farm Botanicals Inc. | Maryland, 20785
 Made in USA



Protective Day Cream
Mineral Sunscreen

**Broad Spectrum
SPF 30**

**Water Resistant
40 minutes**

1.7 FL. OZ (50 mL)

Drug Facts

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Non-Nano Uncoated Zinc Oxide, 2.34%	Sunscreen
Titanium Dioxide, 3.60%	Sunscreen

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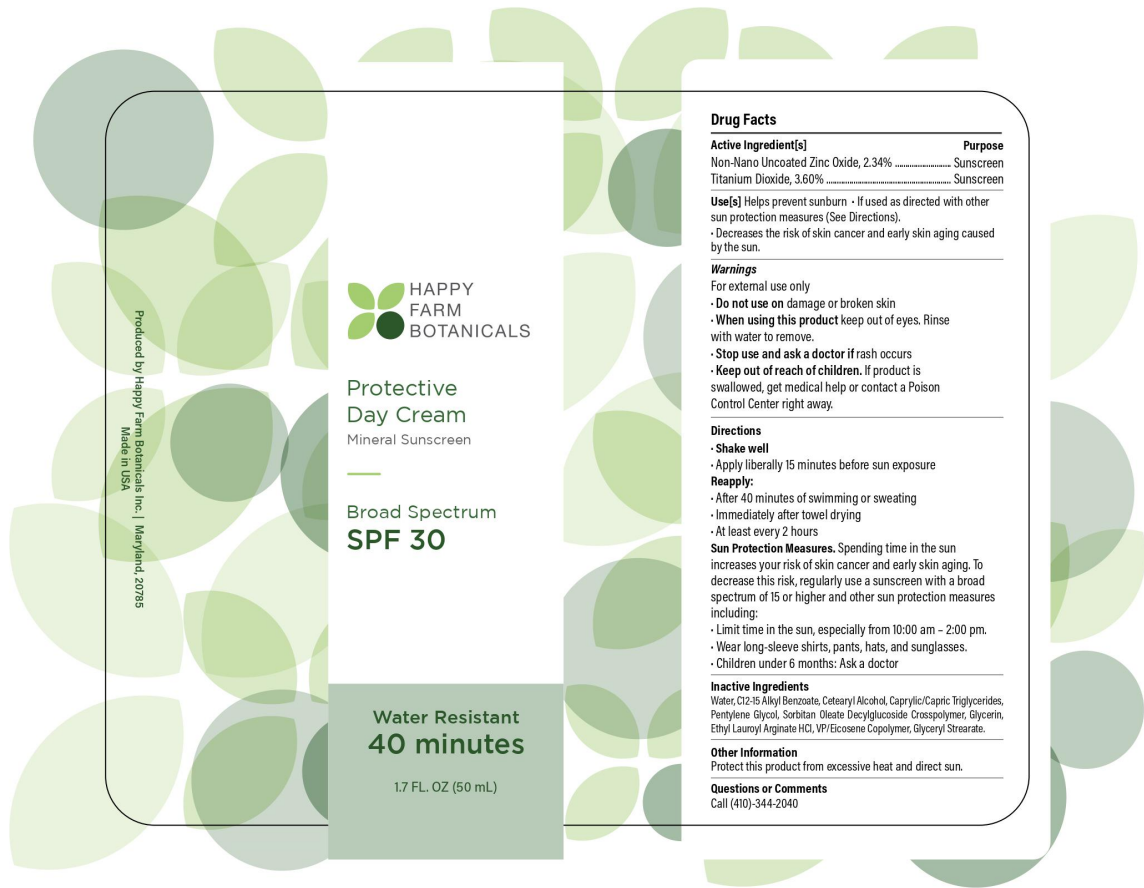
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Water, C12-15 Alkyl Benzoate, Cetearyl Alcohol, Caprylic/Capric Triglycerides, Pentylene Glycol, Sorbitan Oleate Diacylglycoside Crosspolymer, Glycerin, Ethyl Lauroyl Arginate HCl, VP/Eicosene Copolymer, Glyceryl Stearate.

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

Questions or Comments
Call (410)-344-2040

50 ml airless

116.2mm x 112mm



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Mineral Sunscreen

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50 ml airless

116.2mm x 112mm

zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73964-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2.34 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	1 g in 100 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	4 g in 100 g
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	4 g in 100 g
EICOSYL POVIDONE (2 EICOSYL BRANCHES/REPEAT) (UNII: XQQ9MKE2BJ)	2 g in 100 g
PENTYLENE GLYCOL (UNII: 50C1307PZG)	4 g in 100 g
C12-15 ALKYL ETHYLHEXANOATE (UNII: GQJ580CH83)	5 g in 100 g
WATER (UNII: 059QF0KO0R)	65.06 g in 100 g
SORBETH-12/OLEATE/DIMER DILINOLEATE CROSSPOLYMER (UNII: 6287108Q5R)	4 g in 100 g
XANTHAN GUM (UNII: TTV12P4NEE)	1 g in 100 g
ETHYL LAUROYL ARGINATE HYDROCHLORIDE (UNII: XPD6ZY79TB)	2 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	2 g in 100 g

Product Characteristics

Color	white (Cream)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73964-030-01	236 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/04/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/04/2022	

Labeler - Happy Farm Botanicals, Inc. (022653140)

Registrant - Happy Farm Botanicals, Inc. (022653140)

Establishment

Name	Address	ID/FEI	Business Operations
Happy Farm Botanicals, Inc.		022653140	manufacture(73964-030)

Revised: 2/2022

Happy Farm Botanicals, Inc.