ELIZABETH MOTT FACE PRIMER BROAD SPECTRUM SPF 30- titanium dioxide, zinc oxide lotion Prime Enterprises 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.

Elizabeth Mott Thank Me Later Face Primer Blurring Broad Spectrum SPF 30

Active Ingredients

Titanium Dioxide 3%

Zinc Oxide 3%

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 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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- 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 this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including:

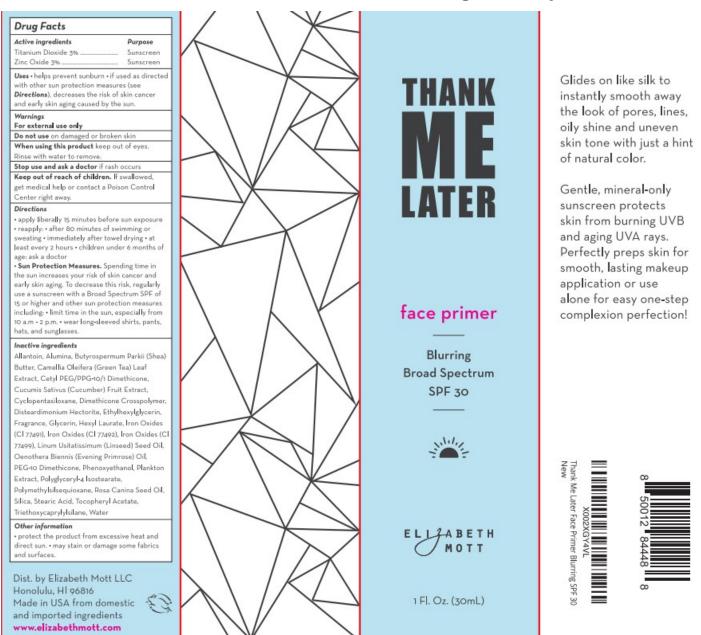
- limit time in the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses

Alumina, Butyrospermum Parkii (Shea) Butter, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Disteardimonium Hectorite, Eucalyptus Globulus Leaf Extract, Fragrance, Glycerin, Hexyl Laurate, Panthenol, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Porphyra Umbilicalis Extract, Silica, Squalane, Stearic Acid, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, Water

Other Information

- protect this product from excessive heat and direct sun.
- may stain or damage some fabrics and surfaces.

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ELIZABETH MOTT FACE PRIMER BROAD SPECTRUM SPF 30

titanium dioxide, zinc oxide lotion

Product	Inform	ation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0573

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30.69 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	30.69 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
SHEA BUTTER (UNII: K49155WL9Y)		
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)		
CYCLOMETHICONE 5 (UNII: OTHT5PCIOR)		
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)		
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)		
GLYCERIN (UNII: PDC6A3C0OX)		
HEXYL LAURATE (UNII: 4CG9F9W01Q)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)		
WATER (UNII: 059QF0KO0R)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)		
ALLANTOIN (UNII: 344S277G0Z)		
CUCUMBER (UNII: YY7C30VXJT)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
FERROUS OXIDE (UNII: G7036X8B5H)		
LINSEED OIL (UNII: 84XB4DV00W)		
ROSA CANINA SEED OIL (UNII: MHT97MG5P8)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)		

Product Characteristics			
Color	brown (Nude)	Score	
Shape		Size	
Flavor		Imprint Code	

Contains

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:58443- 0573-3	30 mL in 1 TUBE; Type 0: Not a Combination Product	04/18/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	04/18/2022	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0573) , manufacture(58443-0573) , label(58443-0573) , analysis (58443-0573)

Revised: 9/2022 Prime Enterprises Inc.