

MATTE DEFENSE MINERAL SUNSCREEN NON TINTED- titanium dioxide, zinc oxide cream

PURE VITALITY SKIN AND BODY, INC

DRUG FACTS

ACTIVE INGREDIENTS:

Titanium Dioxide 8%

Zinc Oxide 16%

PURPOSE:

Sunscreen

Sunscreen

USES:

Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early aging caused by the sun.

WARNINGS:

For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. 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 a broad spectrum SPF value of 15 or higher and other sun protection measures including:

• Limit time in the sun, especially from 10 am- 2 pm

• Wear long sleeve shirts and hats and sunglasses

INACTIVE INGREDIENTS:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

• Protect this product from excessive heat and direct sun

• PA, ++++

DISTRIBUTED BY:

Pure Vitality Skin and Body Inc. - San Diego, CA 92128

www.demmeraeskincares.com

Demmera

SKIN

Matte Defense

Mineral Sunscreen

non tinted

matte

spf

broad spectrum

water resistant

3 85367 20250 3

Net Wt. 1.06 oz (30 g)

MATTE DEFENSE MINERAL SUNSCREEN NON TINTED			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85367-202(NDC:58892-202)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g

Inactive Ingredients				
Ingredient Name				Strength
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
ALUMINA (UNII: LMI26O6933)				
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85367-202-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/02/2022	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M020	11/02/2022	

Labeler - PURE VITALITY SKIN AND BODY, INC (029894266)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85367-202)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85367-202)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85367-202)