

NON-TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
HSC MIAMI, INC

DRUG FACTS

- 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-sleeved shirts, pants, 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 ++++



NON-TINTED
MINERAL SUNSCREEN



3 85376 20250 1

MANUFACTURED FOR:
Holistic Skin Care
Hialeah, FL 33012
(786) 814-9096

BROAD SPECTRUM SPF 40
WATER RESISTANT (80 MINUTES)

NET WT. 1.8 OZ / 53 G

NON-TINTED MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85376-202(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
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALUMINA (UNII: LMI26O6933)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85376-202-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/06/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/06/2025	

Labeler - HSC MIAMI, INC (123498175)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85376-202)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85376-202)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85376-202)