

TINTED PHYSICAL DEFENSE- titanium dioxide, zinc oxide cream
ATLANTA DERMOTOLOGY VEIN & RESEARCH CENTER

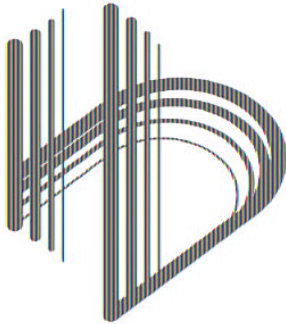
DRUG FACTS (cont)

- 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, Iron Oxide (CI77491), Lauryl PEG/PPG-18/18-Hydrogen Dimethicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

- OTHER INFORMATION:
- Protect this product from excessive heat and direct sun
 - May stain some fabrics
 - PA+++

Manufactured for:
Hamilton Dermatology,
Alpharetta, GA 30022



HAMILTON
DERMATOLOGY

TINTED
PHYSICAL DEFENSE
SPF 40
BROAD SPECTRUM
WATER RESISTANT
80 MINUTES

DR
ACT
Tita
Zinc
USE
as c
me;
the
agi
W/A
Do
skir
occ
kee
rem
chil
hel
Cen
DIR
• Ap
sul
• Re
•
•
• Ch
As

NET WT. 1.8 OZ./53 G.

TINTED PHYSICAL DEFENSE			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85499-203(NDC:58892-203)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	80 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
Inactive Ingredients			

Ingredient Name	Strength
CI 77499 (UNII: XM0M87F357)	
ALUMINA (UNII: LMI26O6933)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CI 77491 (UNII: 1K09F3G675)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CI 77492 (UNII: EX438O2MRT)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85499-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/30/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/30/2019	

Labeler - ATLANTA DERMOTOLOGY VEIN & RESEARCH CENTER (042334099)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85499-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85499-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85499-203)