

TINTED FACIAL SUNSCREEN- titanium dioxide, zinc oxide cream
HELTON SKIN & LASER INSTITUTE

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
- Cleanse thoroughly at nighttime
- PA+++



HELTON
SKIN & LASER
INSTITUTE

*Tinted Facial
 Sunscreen*

SPF 40
Broad Spectrum
Water Resistant
(80 minutes)



Net Wt. 1.8 oz/53 g

DR
 AC
 Tita
 Zinc
 USE
 as c
 me:
 the
 agit
 W/A
 Do
 skir
 occ
 kee
 rem
 chil
 hel
 Gen
 DIR
 • Ap
 sul
 • Re
 •
 •
 • Ch
 As

TINTED FACIAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85679-203(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
ALUMINA (UNII: LMI26O6933)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CI 77491 (UNII: 1K09F3G675)	
CI 77492 (UNII: EX438O2MRT)	
CI 77499 (UNII: XM0M87F357)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85679-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/24/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/24/2019	

Labeler - HELTON SKIN & LASER INSTITUTE (043023268)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85679-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85679-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85679-203)