

ADVANCED FORMULA TINTED- titanium dioxide, zinc oxide cream
CR KEEFE ENTERPRISES, INC.

DRUG FACTS (cont.)

• Sun Protection Measures:

Spending time in the sun increases your risk of skin cancer and early signs of aging. Regular use of sunscreen with a SPF 15 broad spectrum or higher is recommended.

For added protection:

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

- Reef friendly
- Not tested on animals

Made in the USA

Distributed by: Char Skincare
Huntington Beach, California 92647

www.charskincare.com

714-580-4791

NDC: 8588320350

CHAR®

Advanced Formula

40^{SPF}
TINTED

Titanium & Zinc Oxides
SPF 40 Broad Spectrum
Vitamin C & E

Gentle for all skin types
Water Resistant (80 minutes)

DRUG FACTS

ACTIVE INGREDIENTS	PURPOSE
Titanium Dioxide 8%	Sunscreen
Zinc Oxide 3.8%	Sunscreen

USES: Helps prevent sunburn. If used as directed with other sun protection measures (see directions below)

decreases the risk of skin cancer and early signs of aging skin 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 the 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
- Reapply after towel drying
- Reapply every 2 hours

Children under 6 months consult with your doctor before application.



Net. Wt. 1.8 oz/53 g

ADVANCED FORMULA TINTED

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85883-203(NDC:58892-203)
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
CI 77499 (UNII: XM0M87F357)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONOL (2000 CST) (UNII: T74Q12AN6Y)	
ALUMINA (UNII: LMI26O6933)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CI 77492 (UNII: EX438O2MRT)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CI 77491 (UNII: 1K09F3G675)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85883-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/05/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/05/2025	

Labeler - CR KEEFE ENTERPRISES, INC. (042186574)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85883-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85883-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85883-203)