

**CC CREAM MEDIUM140- titanium dioxide, zinc oxide cream**  
**The Creme Shop Inc**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**81123-327 Medium140**

**Active Ingredient**

Titanium Dioxide 5.5%

Zinc Oxide 5.5%

**Purpose**

Helps prevent sunburn.

**Uses**

If uses as directed with other sun protection measures(see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

**Warnings**

For external use only.

Rinse with water to remove.

If swallowed, get medical help or contact Poison Control Center right away.

**Warnings**

Do not use on damaged or broken skin.

**Warnings**

Keep out of reach of children.

**Warnings**

Stop use and ask a doctor if rash occurs.

**Directions**

Apply liberally 15 minutes before sun exposure.

Reapply at least every 2 hours.

Use a water resistant sunscreen if swimming or sweating.

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 of 15 or higher and other sun protection measures including:  
Limit time in the sun, especially from 10 a.m. - 2 p.m.  
Wear long-sleeve shirts, pants, hats, and sunglasses.  
Children under 6 months of age: Ask a doctor.

### **Other Information**

Protect the product in this container from excessive heat and direct sun.

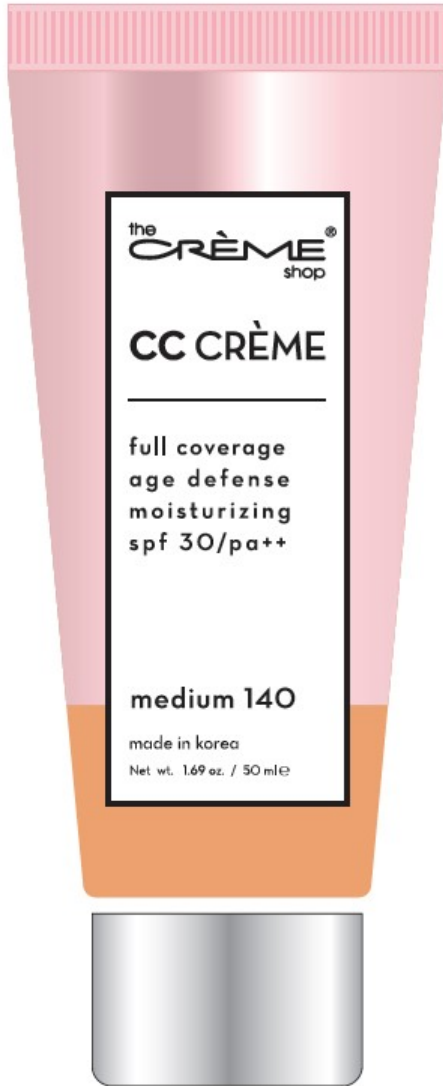
### **Inactive Ingredient**

Water, Sea Water, Dimethicone, Isododecane, Iron Oxide Yellow, Caprylic/Capric Triglyceride, Cetyl PEG/PPG-10/1 Dimethicone, Phenyl Trimethicone, Iron Oxide Red, Sodium Chloride, Butylene Glycol, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Iron Oxide Black, Phenoxyethanol, Sorbitan Isostearate, Triethoxycaprylylsilane, Ceresin, Silica, Magnesium Myristate, Magnesium Stearate, Sorbitan Sesquioleate, 1,2-Hexanediol, Synthetic Wax, Dimethicone/Vinyl Dimethicone Crosspolymer, Aluminum Hydroxide, Ethylhexylglycerin, Dehydroacetic Acid, Distearidimonium Hectorite, Methicone, Adenosine, Propylene Carbonate, Canola Oil, Garcinia Indica Seed Butter, Helianthus Annuus (Sunflower) Seed Oil, Lavandula Angustifolia (Lavender) Oil, Vitis vinifera (Grape) seed oil, Rose Centifolia Flower Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Centella Asiatica Extract, Glycerin, Glycine Soja (Soybean) Seed Extract, Aloe Barbadensis Leaf Extract, Camellia Sinensis Leaf Extract, Cocos Nucifera (Coconut) Fruit Extract, Oryza Sativa (Rice) Extract, Prunus Persica (Peach) Fruit Extract, Fragaria Chiloensis (Strawberry) Fruit Extract, Sodium Hyaluronate

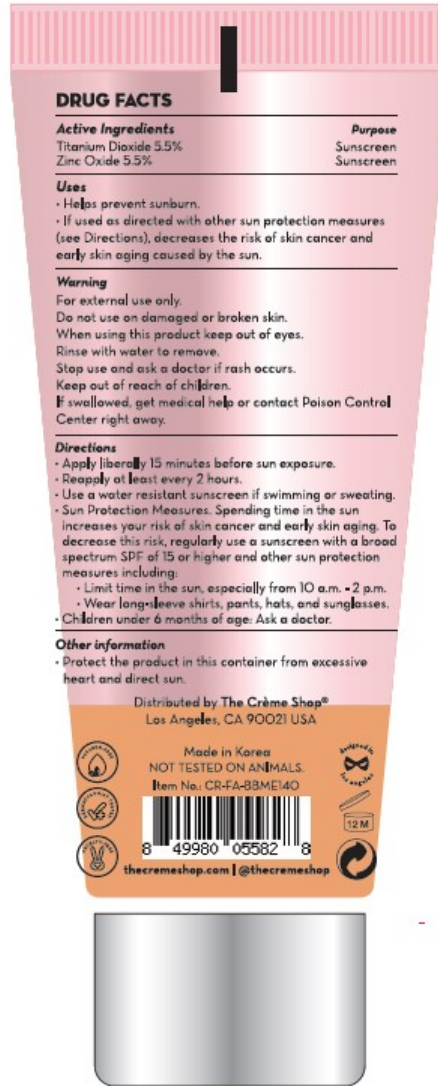
### **Package Label**

# CC Cream Medium 140

Front



Back



PEEL OFF STICKER:



## CC CREAM MEDIUM140

titanium dioxide, zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81123-327
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5.5 mg in 100 mg

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)

ZINC OXIDE

5.5 mg in 100 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>SYNTHETIC WAX (1200 MW)</b> (UNII: Q3Z4BCH099)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>ROSA CENTIFOLIA FLOWER</b> (UNII: CS4TE8FF7O)	
<b>ORANGE</b> (UNII: 5EVU04N5QU)	
<b>SOYBEAN</b> (UNII: L7HT8F1ZOD)	
<b>BEACH STRAWBERRY</b> (UNII: 98542F2TQS)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>RICE GERM</b> (UNII: 7N2B70SFEZ)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>GARCINIA INDICA SEED BUTTER</b> (UNII: US2H3D7800)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>PEACH</b> (UNII: 3OKE88I3QG)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>COCONUT</b> (UNII: 3RT3536DHY)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>METHICONE (20 CST)</b> (UNII: 6777U11MKT)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>ADENOSINE</b> (UNII: K72T3FS567)	
<b>CANOLA OIL</b> (UNII: 331KBJ17RK)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)	
<b>PHENYL TRIMETHICONE</b> (UNII: DROK5NOJ4R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM MYRISTATE</b> (UNII: Z1917F0578)	

**SORBITAN SESQUIOLEATE** (UNII: 0W8RRI5W5A)

**ALUMINUM HYDROXIDE** (UNII: 5QB0T2IUN0)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81123-327-01	50 mg in 1 TUBE; Type 0: Not a Combination Product	12/11/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/11/2020	

**Labeler** - The Creme Shop Inc (052907070)

**Registrant** - The Creme Shop Inc (052907070)

### Establishment

Name	Address	ID/FEI	Business Operations
Anneu Co., Ltd.		690377762	manufacture(81123-327)

Revised: 5/2021

The Creme Shop Inc