

**CC CREAM TAN200- zinc oxide, titanium dioxide 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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**81123-309 Tan200**

**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 Ingredients**

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 Tan200

Front

Back



PEEL OFF STICKER:

PEEL

**Inactive Ingredients (cont.)**

Water/Aqua, Dimethicone, Isododecane, Sea Water, Copolyol/Capric Triglyceride, Cetyl PEG/PPG-10/1 Dimethicone, Phenyl Trimethicone, Sodium Chloride, Butylene Glycol, Phenylethanol, Lauryl PEG-9 Polydimethylsilyloxyethyl Dimethicone, Sorbitan Isostearate, Ceresin, Triethoxypropylsiloxane, Sorbitan Sesquisebacate, 1,2-Hexanediol, Synthetic Wax, Aluminum Hydroxide, Ethylhexylglycerin, Dihydroxyacetone, Magnesium Myristate, Magnesium Stearate, Dimethicone/Vinyl Dimethicone Crosspolymers, Silica, Disodium EDTA, Disodium EDTA, Adenosine, Propylene Carbonate, Canola Oil, Garcinia Indica Seed Butter, Helianthus Annuus (Sunflower) Seed Oil, Lavandula Angustifolia (Lavender) Oil, Vitis vinifera (Grape) seed oil, Rosa Centrifolia Flower Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Cardella Alonina Extract, Melaleuca, Glycerin, Glycine Soja (Soybean) Seed Extract, Alsea Barbadiana 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, May contain (+/-): Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891), Zinc Oxide (CI 77947)

## CC CREAM TAN200

zinc oxide, titanium dioxide cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:81123-309 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength         |
|---|-------------------|------------------|
| <b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)             | ZINC OXIDE        | 5.5 mg in 100 mL |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 5.5 mg in 100 mL |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)   |          |
| <b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)   |          |
| <b>ADENOSINE</b> (UNII: K72T3FS567)  |          |
| <b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)  |          |
| <b>ISODODECANE</b> (UNII: A8289P68Y2)  |          |
| <b>MAGNESIUM MYRISTATE</b> (UNII: Z1917F0578)  |          |
| <b>SORBITAN SESQUIOLEATE</b> (UNII: 0W8RRI5W5A)                                      |          |
| <b>SYNTHETIC WAX (1200 MW)</b> (UNII: Q3Z4BCH099)                                    |          |
| <b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5) |          |
| <b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)   |          |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)   |          |
| <b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)                                  |          |
| <b>METHICONE (20 CST)</b> (UNII: 6777U11MKT)   |          |
| <b>GARCINIA INDICA SEED BUTTER</b> (UNII: US2H3D7800)                                |          |
| <b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)   |          |
| <b>PEACH</b> (UNII: 30KE88I3QG)  |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)   |          |
| <b>WATER</b> (UNII: 059QF0KO0R)  |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)  |          |
| <b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)  |          |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)  |          |
| <b>DEHYDROACETIC ACID</b> (UNII: 2KAG279R6R)   |          |
| <b>CANOLA OIL</b> (UNII: 331KBJ17RK)   |          |
| <b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)   |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)  |          |
| <b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)                                       |          |
| <b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)                                    |          |
| <b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)  |          |
| <b>ROSA CENTIFOLIA FLOWER</b> (UNII: CS4TE8FF7O)                                     |          |
| <b>ORANGE</b> (UNII: 5EVU04N5QU)   |          |
| <b>SOYBEAN</b> (UNII: L7HT8F1ZOD)  |          |
| <b>CERESIN</b> (UNII: Q1LS2UJO3A)  |          |
| <b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U)  |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)   |          |
| <b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)   |          |
| <b>RICE GERM</b> (UNII: 7N2B70SFEZ)  |          |
| <b>BEACH STRAWBERRY</b> (UNII: 98542F2TQS)   |          |
| <b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)   |          |
| <b>COCONUT</b> (UNII: 3RT3536DHY)  |          |
| <b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)  |          |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)                                 |          |
| <b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)                     |          |
| <b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)   |          |
| <b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)           |          |
| <b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)   |          |

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:81123-309-01 | 50 mL in 1 TUBE; Type 0: Not a Combination Product | 11/20/2020           |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 11/20/2020           |                    |

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

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

### Establishment

| Name           | Address | ID/FEI    | Business Operations    |
|----------------|---------|-----------|------------------------|
| ANNE Cosmetics |         | 690377762 | manufacture(81123-309) |

Revised: 5/2022

The Creme Shop Inc