

CC CREAM MEDIUM120- 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.

81123-304 Medium120

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

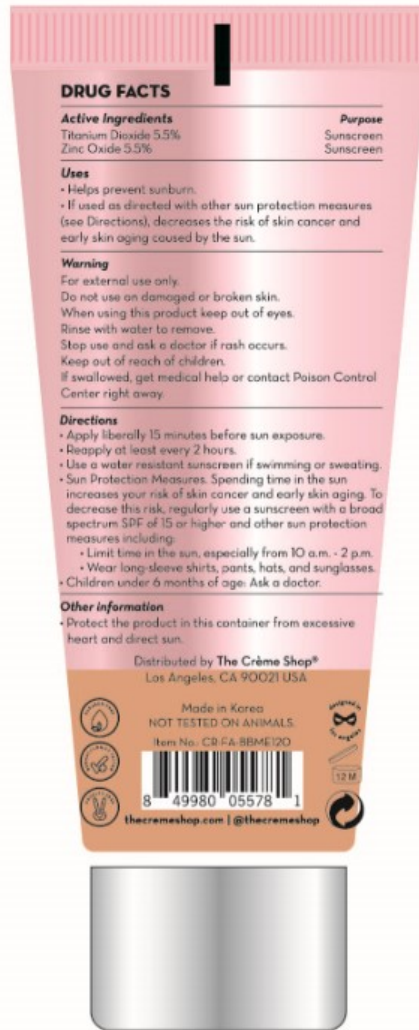
Package Label

CC Cream Medium 120

Front



Back



PEEL OFF STICKER:



CC CREAM MEDIUM120

zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81123-304
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
CANOLA OIL (UNII: 331KBJ17RK)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)	
ORANGE (UNII: 5EVU04N5QU)	
SOYBEAN (UNII: L7HT8F1ZOD)	
CERESIN (UNII: Q1LS2UJO3A)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
RICE GERM (UNII: 7N2B70SFEZ)	
BEACH STRAWBERRY (UNII: 98542F2TQS)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
COCONUT (UNII: 3RT3536DHY)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
ADENOSINE (UNII: K72T3FS567)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ISODODECANE (UNII: A8289P68Y2)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
GARCINIA INDICA SEED BUTTER (UNII: US2H3D7800)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
PEACH (UNII: 3OKE88I3QG)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81123-304-01	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(81123-304)

Revised: 4/2022

The Creme Shop Inc