

CC CREAM DEEP240- 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.

81123-313 Deep240

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 Deep240

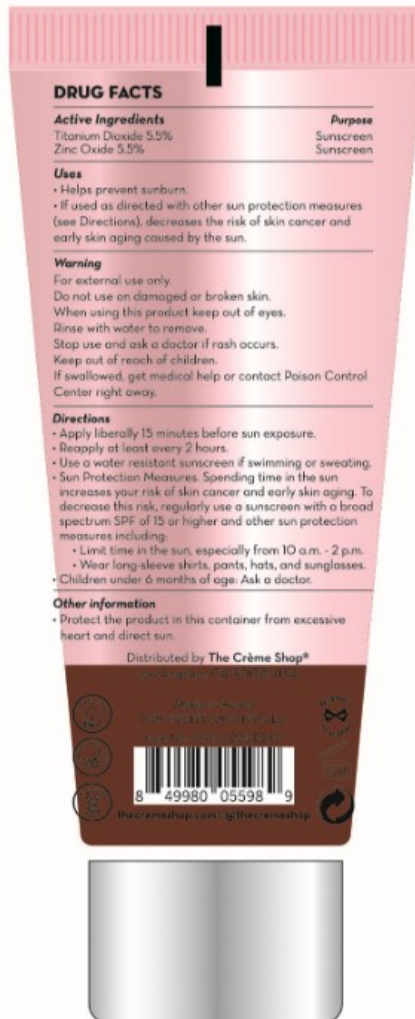
Front

Back

PEEL OFF STICKER:

Inactive Ingredients (cont.)

Water/Aqua, Dimethicone, Isodecane, Sea Water, Caprylic/Capric Triglyceride, Cetyl PEG/PPG-10/1 Dimethicone, Phenyl Trimethicone, Sodium Chloride, Butylene Glycol, Phenoxyethanol, Lauryl PEG-9 Polydimethylsilyloxyethyl Dimethicone, Sorbitan Isodecanoate, Caranin, Triethoxycaprylylsilane, Sorbitan Sesquioleate, 1,2-Hexanediol, Synthetic Wax, Aluminum Hydroxide, Ethylhexylglycerin, Dihydroxyacetone Acid, Magnesium Myristate, Magnesium Stearate, Dimethicone/Vinyl Dimethicone Crosspolymer, Silica, Dicalciummagnesium Hexafluoride, Adenosine, Propylene Carbonate, Canola Oil, Garcinia Indica Seed Butter, Helianthus Annuus (Sunflower) Seed Oil, Lavandula Angustifolia (Lavender) Oil, Vitis vinifera (Grape) seed oil, Base Camellia Flower Extract, Citrus Aurantium Dulcis (Orange) Fruit Extract, Castilleja Asiatica Extract, Menthacene, Glycerin, Glycine Soja (Soybean) Seed Extract, Aloe Barbadosensis Leaf Extract, Camellia Sinesis Leaf Extract, Cocos Nucifera (Coconut) Fruit Extract, Oryza Sativa (Rice) Extract, Prunus Persica (Peach) Fruit Extract, Fragaria Chiloensis (Strawberry) Fruit Extract, Sodium Hyaluronate, Methyl Methacrylate (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891), Zinc Oxide (CI 77947)



CC CREAM DEEP240			
titanium dioxide, zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81123-313
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
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
CERESIN (UNII: Q1LS2UJO3A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ISODODECANE (UNII: A8289P68Y2)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GARCINIA INDICA SEED BUTTER (UNII: US2H3D7800)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
BEACH STRAWBERRY (UNII: 98542F2TQS)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CANOLA OIL (UNII: 331KBJ17RK)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
ADENOSINE (UNII: K72T3FS567)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)	
ORANGE (UNII: 5EVU04N5QU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
RICE GERM (UNII: 7N2B70SFEZ)	
PEACH (UNII: 3OKE88I3QG)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SOYBEAN (UNII: L7HT8F1ZOD)	
COCONUT (UNII: 3RT3536DHY)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81123-313-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	12/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/08/2020	

Labeler - The Creme Shop Inc (052907070)

Registrant - The Creme Shop Inc (052907070)

Establishment

Name	Address	ID/FEI	Business Operations
ANNE Cosmetics		690377762	manufacture(81123-313)

Revised: 4/2022

The Creme Shop Inc