

DR YOUNG PROTECT PREVENT 2P PEARL BRIGHTENING BALM- titanium dioxide, octinoxate, zinc oxide cream

Tdc, Co. Ltd

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.

ACTIVE INGREDIENT

Active ingredients: Titanium Dioxide 8.90%, Ethylhexyl Methoxycinnamate 6.50%, Zinc Oxide 0.90%

INACTIVE INGREDIENT

Inactive ingredients: Water, Cyclopentasiloxane, Cyclohexasiloxane, Glycerin, Dipropylene Glycol, Hexyl Laurate, Butylene Glycol Dicaprylate/Dicaprate, Cetyl PEG/PPG-10/1 Dimethicone, Bentonite, Chrysanthellum Indicum Extract, Magnesium Sulfate, Pearl Powder, Magnolia Liliflora Flower Extract, Liliium Candidum Flower Extract, Convallaria Majalis Bulb/Root Extract, Butyrospermum Parkii (Shea) Butter, Magnolia Kobus Bark Extract, Thujopsis Dolabrata Branch Extract, Camellia Sinensis Leaf Extract, Citrus Grandis (Grapefruit) Fruit Extract, Centella Asiatica Extract, Althaea Rosea Flower Extract, Aloe Barbadensis Leaf Extract, Silica, CI 77492, CI 77491, CI 77499, Ultramarines, Sorbitan Isostearate, Tocopheryl Acetate, Ascorbyl Glucoside, Allantoin, Ceramide 3, Disodium EDTA, Methylparaben, Propylparaben, Fragrance

PURPOSE

Purpose: Sunscreen

WARNINGS

Warning: 1) For external use only. 2) Consult a dermatologist if the first sign occurs like red spot, swelling, itching, or any allergic reactions. 3) Avoid direct contact with eyes. 4) If contact occurs, flush thoroughly with water. 5) If swallowed, get medical help or contact a Poison Control Center right away. 6) Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging. Storage and cautions for handling: 1) Keep out of reach of children. 2) Keep away from high or low temperature and direct sunlight.

DESCRIPTION

Uses: - Ultralight, dark toned beauty balm to protect, tint, and moisturize skin - Features SPF 35 PA++ sun protection

Directions: Apply moderate amount on entire face after basic skin care.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Dr. Young
Pearl Brightening Balm
[Protect Prevent]

Uses

Ultralight, dark toned beauty balm to protect, tint, and moisturize skin

Features SPF 35 PA++ sun protection

PURPOSE

Sunscreen

Directions

Apply moderate amount on entire face after basic skin care.

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Manufactured for TDC Co., Ltd.

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Questions

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ACTIVE INGREDIENTS

Titanium Dioxide 8.90%

Ethylhexyl Methoxycinnamate 6.50%

Zinc Oxide 0.90%

INACTIVE INGREDIENTS

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titanium dioxide, octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43948-1310
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	2.67 g in 30 mL
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	1.95 g in 30 mL
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.27 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43948-1310-2	1 in 1 CARTON	10/01/2017	
1	NDC:43948-1310-1	30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2017	

Labeler - Tdc, Co. Ltd (687479378)

Registrant - Tdc, Co. Ltd (687479378)

Establishment

Name	Address	ID/FEI	Business Operations
Biocostec Co., Ltd.		690407325	manufacture(43948-1310)