

CREAM- titanium dioxide cream
Oxygen Development LLC

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.

Bare Minerals 5 in 1 BB advanced performance cream eyeshadow broad spectrum spf 15 - soft shell

Active Ingredient

Titanium Dioxide 17%. Purpose: Sunscreen

Purpose

Sunscreen

Uses

helps prevent sunburn if used as directed with other sun protection measures.
Decreased the risk of skin cancer and early skin aging caused by the sun

Warnings

for external use only

Do not use

on damaged or broken skin

When using

this product, keep out of eyes. Rinse with water to remove

Stop use

and ask a doctor if rash occurs

Keep out of reach of children

If product is swallowed, get medical help or contact a poison control center right away

Directions

for sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months ask a doctor

Sun protection measures

spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the 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 10am - 2pm
- wear long-sleeve shirts, pants, hats, and sunglasses

Inactive ingredients

isododecane, disteardimonium hectorite, Polymethylsilsesquioxane, Caprylic/Capric Triglyceride, propylene carbonate, silica, Trimethylsiloxysilicate, Dipalmitoyl Hydroxyproline, Mangifera Indica (Mango) Seed Butter, Carthamus Tinctorius (Safflower) Seed Oil, Camellia Oleifera Leaf Extract, Acrylates Copolymer, Diacetyl Boldine, Calcium Sodium Borosilicate, Calcium Aluminum Borosilicate, tin oxide, phenoxyethanol, may contain: mica, carmine, titanium dioxide, iron oxides, Bismuth Oxychloride, chromium hydroxide green, chromium oxide greens, ferric ferrocyanide, manganese violet, ultramarines

other information

protect this product from excessive heat and direct sun

package label

BARB ESSENTIALS
 91 STEVENSON STREET, 2ND FLOOR
 SAN FRANCISCO, CA 94104

Re: Sourcing
 From: Christine (BarType)
 Date: 5/20/14

Project: Net Eyeshadow box 01--
 SOFT SHELL

SKU Reference Number:
 70592 (Net 70592 (gross))

File Name:
 MKT_0101_Eyeshadow_BOX_Mktfigs_01_02014

Size: 150° x 150° x 3.408"

Sides: 2

Stock: 15 pr ctls

Colors: 01 (CMYK: 4 PMS: black 7 C PMS: 225a)

■ PMS 225a

■ PMS Black 7 C

Coating: CA Satin AQ

Additional Finishes: NA

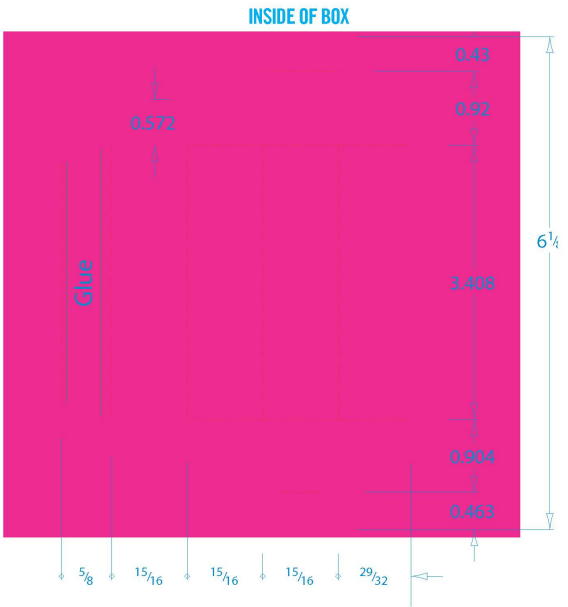
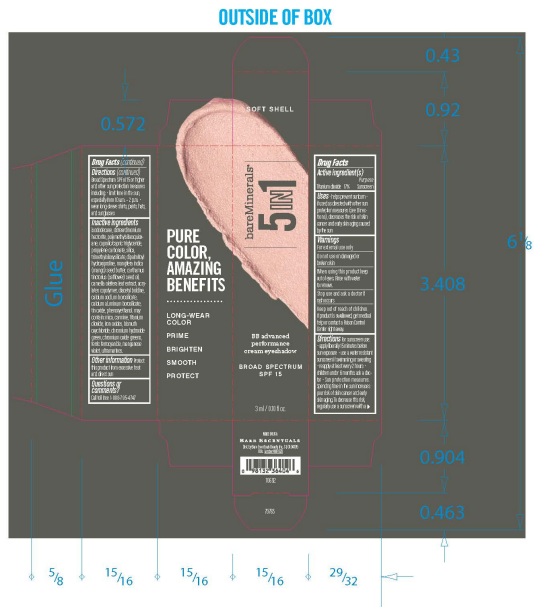
Special Instructions: Match to Proof

Beads: 100 all around

Press Check Required: Yes

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For any questions, please contact Doreen (415-499-9593), Nancy (415-499-9205), Cheryl (415-499-6440) or Michelle (415-499-2244).



CREAM

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-080
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	17 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
TRIMETHYLSILOXYSILICATE (M/Q 0.66) (UNII: 5041RX63GN)	
MANGO SEED OIL (UNII: K8LOR30915)	
ACRYLATES CROSSPOLYMER-6 (UNII: 4GXD0Q30S3)	
ISODODECANE (UNII: A8289P68Y2)	
MICA (UNII: V8A1AW0880)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	

PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-080-08	1 in 1 CARTON	02/22/2021	02/10/2023
1	NDC:61354-080-02	3 mg in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/22/2021	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-080)

Revised: 2/2023

Oxygen Development LLC