

3CE EYE SHADOW PALETTE SIENNA- titanium dioxide powder

Nanda 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 Ingredient: Titanium Dioxide 5.9%

INACTIVE INGREDIENT

Inactive Ingredients:

A) Mica (CI 77019), Talc, Glass, Neopentyl Glycol Diethylhexanoate, Iron Oxides (CI 77491), Phenyl Trimethicone, Calcium Aluminum Borosilicate, Nylon-12, Diisostearyl Malate, Dipentaerythrityl Hexahydroxystearate/Hexastearate/Hexarosinate, Octyldodecyl Stearoyl Stearate, Isostearyl Neopentanoate, Magnesium Myristate, Magnesium Stearate, Carmine (CI 75470), Silica, Polybutene, Iron Oxides (CI 77499), Propanediol, Dimethicone, Ultramarines (CI 77007), Triethoxycaprylylsilane, Sodium Dehydroacetate, Hydrogenated Lecithin, Tin Oxide (CI 77861)

B)~D) Mica (CI 77019), Talc, Glass, Titanium Dioxide (CI 77891), Neopentyl Glycol Diethylhexanoate, Iron Oxides (CI 77491), Phenyl Trimethicone, Calcium Aluminum Borosilicate, Nylon-12, Diisostearyl Malate, Dipentaerythrityl Hexahydroxystearate/Hexastearate/Hexarosinate, Octyldodecyl Stearoyl Stearate, Isostearyl Neopentanoate, Magnesium Myristate, Magnesium Stearate, Carmine (CI 75470), Silica, Polybutene, Iron Oxides (CI 77499), Propanediol, Dimethicone, Ultramarines (CI 77007), Triethoxycaprylylsilane, Sodium Dehydroacetate, Hydrogenated Lecithin, Tin Oxide (CI 77861)

PURPOSE

Purpose: Sunscreen

CAUTION

CAUTION: 1. Keep it out of children's reach 2. Keep it away from expose to sunlight, high and low temperatures.

DESCRIPTION

INSTRUCTIONS: Eye shadow palette with harmonious colors that magnify the hues and light.

Directions: Gently apply on skin with its smooth sliding texture for a clean and luxurious finish

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



3CE eye shadow palette #SIENNA

FUNCTION: Eye shadow INSTRUCTIONS: Eye shadow palette with harmonious colors that magnify the hues and light COUNTRY OF MANUFACTURE: South Korea NET Wt.: 8g DIRECTIONS: Gently apply on skin with its smooth sliding texture for a clean and luxurious finish ACTIVE INGREDIENT: Titanium Dioxide 5.9% INACTIVE INGREDIENTS: A) Mica (CI 77019), Talc, Glass, Neopentyl Glycol Diethylhexanoate, Iron Oxides (CI 77491), Phenyl Trimethicone, Calcium Aluminum Borosilicate, Nylon-12, Disostearyl Malate, Dipentaerythryl Hexahydroxystearate/Hexastearate/Hexarostearate, Octyldodecyl Stearyl Stearate, Isostearyl Neopentanoate, Magnesium Myristate, Magnesium Stearate, Carmine (CI 75201), Silica, Polybutene, Iron Oxides (CI 77499), Propenediol, Dimethicone, Ultramarines (CI 77007), Triethoxycaprylsilane, Sodium Dihydroxostearate, Hydrogenated Lecithin, Tin Oxide (CI 77861) B) (I) Mica (CI 77019), Talc, Glass, Titanium Dioxide (CI 77891), Neopentyl Glycol Diethylhexanoate, Iron Oxides (CI 77491), Phenyl Trimethicone, Calcium Aluminum Borosilicate, Nylon-12, Disostearyl Malate, Dipentaerythryl Hexahydroxystearate/Hexastearate/Hexarostearate, Octyldodecyl Stearyl Stearate, Isostearyl Neopentanoate, Magnesium Myristate, Magnesium Stearate, Carmine (CI 75201), Silica, Polybutene, Iron Oxides (CI 77499), Propenediol, Dimethicone, Ultramarines (CI 77007), Triethoxycaprylsilane, Sodium Dihydroxostearate, Hydrogenated Lecithin, Tin Oxide (CI 77861) PURPOSE: Sunscreen CAUTION: 1. Keep it out of children's reach 2. Keep it away from exposure to sunlight, high and low temperatures

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titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-066
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	0.47 g in 8 g

Inactive Ingredients

Ingredient Name	Strength
Mica (UNII: V8A1AW0880)	
Talc (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:60764-066-02	1 in 1 CARTON	08/20/2016	
1	NDC:60764-066-01	8 g in 1 CONTAINER; 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	08/20/2016	

Labeler - Nanda Co., Ltd (557816075)

Registrant - Nanda Co., Ltd (557816075)

Establishment

Name	Address	ID/FEI	Business Operations
Nanda Co., Ltd		557816075	repack(60764-066)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-066)

Revised: 10/2016

Nanda Co., Ltd