

### **3CE TRIPLE SHADOW BODY TO BODY- 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.*

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#### **ACTIVE INGREDIENT**

Active Ingredient: Titanium Dioxide 12.0%

#### **INACTIVE INGREDIENT**

Inactive Ingredients: Mica (CI 77019), Talc, Calcium Sodium Borosilicate, Synthetic Fluorophlogopite, Neopentyl Glycol Diethylhexanoate, Phenyl Trimethicone, Nylon-12, Magnesium Myristate, Magnesium Stearate, Diisostearyl Malate, Dipentaerythrityl Hexahydroxystearate/Hexastearate/Hexarosinate, Octyldodecyl Stearoyl Stearate, Isostearyl Neopentanoate, Polypropylene, Methyl Methacrylate Crosspolymer, Polybutene, Synthetic Wax, Propanediol, PTFE, Triethoxycaprylylsilane, Dimethicone, Tocopheryl Acetate, Tin Oxide (CI 77861), Sodium Dehydroacetate, Carmine (CI 75470), Iron Oxides (CI 77491)

#### **PURPOSE**

Purpose: Sunscreen

#### **CAUTION**

CAUTION: 1. Discontinue use and consult a doctor when - your skin irritates, swells, itches, shows spots on areas applied - your skin reacts similarly with above when exposed to sunlight 2. Avoid applying on wounded, irritated, troubled areas 3. After the use - keep the cap closed - keep it out of children's reach - keep it away from exposure to sunlight, high and low temperatures

#### **DESCRIPTION**

INSTRUCTIONS: Glittery and pigmented triple eye shadow that will give feminized eyes.

Directions: Layer/mix colors together and express different looks

#### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



**3CE triple shadow #BODY TO BODY**

FUNCTION: Eye shadow  
 INSTRUCTIONS: Glittery and pigmented triple eye shadow that will give feminized eyes DIRECTIONS: Layer/mix colors together and express different looks COUNTRY OF MANUFACTURE: South Korea NET Wt. 3.5g  
 ACTIVE INGREDIENT: Titanium Dioxide 12.0%  
 INACTIVE INGREDIENTS: Mica [CI 77019], Talc, Calcium Sodium Borosilicate, Synthetic Fluorphlogopite, Neopentyl Glycol Diethylhexanoate, Phenyl Trimethicone, Nylon-12, Magnesium Myristate, Magnesium Stearate, Diisostearyl Malate, Dipentaerythryl Hexahydroxystearate/Hexastearate/Hexarosinate, Octyldodecyl Stearoyl Stearate, Isostearyl Neopentanoate, Polypropylene, Methyl Methacrylate, Copolymer, Polybutene, Synthetic Wax, Propanediol, PTFE, Triethoxycaprylylsilane, Dimethicone, Tocopheryl Acetate, Tin Oxide [CI 77861], Sodium Dehydroacetate, Carmine [CI 75470], Iron Oxides [CI 77491]  
 PURPOSE: Sunscreen  
 CAUTION: 1. Discontinue use and consult a doctor when 1) your skin irritates, swells, itches, shows spots on areas applied 2) your skin reacts similarly with above when exposed to sunlight 2. Avoid applying on wounded, irritated, troubled areas 3. After the use 1) keep the cap closed 2) keep it out of children's reach 3) keep it away from exposure to sunlight, high and low temperatures

3CE TRIPLE SHADOW BODY TO BODY			
titanium dioxide powder			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-022
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)		Titanium Dio xide	0.42 g in 3.5 g
Inactive Ingredients			
Ingredient Name		Strength	
Mica (UNII: V8A1AW0880)			
Talc (UNII: 7SEV7J4R1U)			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-022-02	1 in 1 CARTON	08/01/2016	
1	NDC:60764-022-01	3.5 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	08/01/2016	

**Labeler** - Nanda Co., Ltd (557816075)**Registrant** - Nanda Co., Ltd (557816075)**Establishment**

Name	Address	ID/FEI	Business Operations
Nanda Co., Ltd		557816075	repack(60764-022)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-022)

Revised: 9/2016

Nanda Co., Ltd