

### **3CE PORE SILKY BALM- 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 0.5%

#### **INACTIVE INGREDIENT**

Inactive Ingredients: Dimethicone, Silica, Phenyl Trimethicone, Isotridecyl Isononanoate, Methyl Methacrylate Crosspolymer, Sorbitan Olivolate, Microcrystalline Wax, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Stearoyl Inulin, Polyethylene, Talc, Hydroxyapatite, Acetylated Sucrose Distearate, Diisostearyl Malate, Butylparaben, Fragrance (Parfum), Methicone, Polyglyceryl-2 Triisostearate, Yellow 5 Lake (CI 19140), Macadamia Integrifolia Seed Oil, Butyrospermum Parkii (Shea) Butter, Argania Spinosa Kernel Oil, Polyvinylalcohol Crosspolymer, Nylon-12 Fluorescent Brightener 230 Salt

#### **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: Primer that conceals your rough, bumpy skin for a smooth canvas finish.

Directions: Apply on concerned areas with wide pores then proceed to base make-up.

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



**3CE pore silky balm**

**FUNCTION:** Base **INSTRUCTIONS:** Primer that conceals your rough, bumpy skin for a smooth canvas finish. **DIRECTIONS:** Apply on concerned areas with wide pores then proceed to base make-up  
**COUNTRY OF MANUFACTURE:** South Korea **NET Wt. 25g** **ACTIVE INGREDIENT:** Titanium Dioxide(5%)  
**INACTIVE INGREDIENTS:** Dimethicone, Silica, Phenyl Trimethicone, Isotridecylbiscinnamate, Methyl Methacrylate Crosspolymer, Sorbitan Monooleate, Microcrystalline Wax, Vinyl Dimethicone Methacrylate, Stearic Acid, Stearalkyl Dimethacrylate, Stearyl Inulin, Polyethylene, Talc, Hydroxyapatite, Acetylated Sucrose Distearate, Disostearyl Malate, Butylparaben, Fragrance/Parfum, Methicone, Polyglyceryl-2 Trisostearate, Yellow 5 Lake CI 19140, Macadamia Integritolia Seed Oil, Buriti Permu (Puriti) Shell Butter, Argan Seed Oil, Polyvinylacrylate Crosspolymer, Nylon 12 Fluorescent Brightener 230 Salt. **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 winded, irritated, or abraded areas. 3. After the use 1) keep the cap closed 2) keep it out of children's reach. 3) keep it away from expose to sunlight, high and low temperatures.



**3CE PORE SILKY BALM**

titanium dioxide powder

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60764-014
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	Titanium Dioxide	0.12 g in 25 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Phenyl Trimethicone</b> (UNII: DR0K5NOJ4R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-014-02	1 in 1 CARTON	08/10/2016	
1	NDC:60764-014-01	25 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	08/10/2016	

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Nanda Co., Ltd		557816075	repack(60764-014)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-014)

Revised: 9/2016

Nanda Co., Ltd