

### **3CE LIP COLOR 401 SCANDAL- titanium dioxide lipstick**

**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 1.5%

#### **INACTIVE INGREDIENT**

Inactive Ingredients: Triethylhexanoin, Polyglyceryl-2 Triisostearate, Trimethylolpropane Tricaprylate/Tricaprate, Isononyl Isononanoate, Mica (CI 77019), Diisostearyl Malate, Diglyceryl Sebacate/Isopalmitate, Silica, Ceresin, Ozokerite, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Pentaerythrityl Tetraoisostearate, Red 6 (CI 15850), Red 28 Lake (CI 45410), VP/Hexadecene Copolymer, Microcrystalline Wax, Sorbitan Isostearate, Silica Silylate, Polyethylene, Synthetic Wax, Silica Dimethyl Silylate, Polyglyceryl-2 Diisostearate, Methicone, Ethylene/Propylene Copolymer, Cholesteryl Macadamiate, Methylparaben, Mangifera Indica (Mango) Seed Butter, Butyrospermum Parkii (Shea) Butter, Water, Butylene Glycol, Diamond powder, Amethyst Powder, Pearl Powder, Tourmaline

#### **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 expose to sunlight, high and low temperatures

#### **DESCRIPTION**

INSTRUCTIONS: A rich color lipstick that moistly adheres to lips.

Directions: Twist to dispense makeup and apply evenly to lips

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



3CE lip color #401 SCANDAL FUNCTION: Lipstick INSTRUCTIONS: Creamy matte lipstick that adds tension to your lips DIRECTIONS: Twist to dispense makeup and apply evenly to lips COUNTRY OF MANUFACTURE: South Korea NET Wt. 3.5g ACTIVE INGREDIENT: Titanium Dioxide 1.5% INACTIVE INGREDIENTS: Triethylhexanoin, Ethylhexyl Hydroxystearate, Isononyl Isononanoate, Disostearyl Msiate, Polyglyceryl-2 Trisostearate, Silica, Alumina, Microcrystalline Wax, Ceresin, Ozokerite, Diglyceryl Sebacate/Isopalmitate, Red 6 (CI 15850), Octyldodecanol, Red 28 Lake (CI 45410), VP/Hexadecene Copolymer, Dicalcium Phosphate, Sorbitan Isostearate, Euphorbia Cerifera (Candelilla) Wax, Polyethylene, Mica (CI 77019), Silica Dimethyl Silylate, Polyglyceryl-2 Disostearate, Tocopheryl Acetate, Mangifera Indica (Mango) Seed Butter, Butyrospermum Parkii (Shea) Butter, Diamond powder, Pentaerythrityl Tetraostearate, Water, Butylene Glycol, Amethyst Powder, Pearl Powder, Tourmaline, Methylparaben 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 LIP COLOR 401 SCANDAL

titanium dioxide lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-069
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 Dioxide	0.05 g in 3.5 g

### Inactive Ingredients

Ingredient Name	Strength
Triethylhexanoin (UNII: 7K3W1BIU6K)	
Isononyl Isononanoate (UNII: S4V5BS6GCX)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-069-02	1 in 1 CARTON	08/01/2016	
1	NDC:60764-069-01	3.5 g 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 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(60764-069)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-069)

Revised: 10/2016

Nanda Co., Ltd