

### **3CE LIP COLOR 506 DAILY LADY- 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 3.6%

#### **INACTIVE INGREDIENT**

Inactive Ingredients: Diisostearyl Malate, Ricinus Communis (Castor) Seed Oil, Caprylic/Capric Triglyceride, Triethylhexanoin, Mica (CI 77019), Pentaerythrityl Tetraethylhexanoate, Ozokerite, Diglyceryl Sebacate/Isopalmitate, Petrolatum, Ceresin, Bis-Diglyceryl Polyacyladipate-2, Polyglyceryl-2 Triisostearate, Dicalcium Phosphate, Talc, Euphorbia Cerifera (Candelilla) Wax, Glyceryl Ethylhexanoate/Stearate/Adipate, Hydrogenated Vegetable Oil, Polyethylene, VP/Hexadecene Copolymer, Sorbitan Isostearate, Silica Dimethyl Silylate, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Methicone, Red 7 (CI 15850:1), Polyglyceryl-2 Diisostearate, Tocopheryl Acetate, Phytosteryl Macadamiate, Glyceryl Caprylate, Mangifera Indica (Mango) Seed Butter, Butyrospermum Parkii (Shea) Butter, Water, Butylene Glycol, Diamond powder, Amethyst Powder, Pearl Powder, Tourmaline, Methylparaben

#### **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 506 DAILY LADY

titanium dioxide lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60764-075
<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 Dio xide	0.12 g in 3.5 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Diisostearyl Malate</b> (UNII: QBS8A3XZGQ)	
<b>Mica</b> (UNII: V8A1AW0880)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-075-02	1 in 1 CARTON	08/01/2016	
1	NDC:60764-075-01	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(60764-075)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-075)

Revised: 10/2016

Nanda Co., Ltd