

### **3CE LIP COLOR 803 CLASSIC ROSY- 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 2.9%

#### **INACTIVE INGREDIENT**

Inactive Ingredients: Diisostearyl Malate, Triethylhexanoin, Silica, EthylhexylHydroxystearate, IsononylIsononanoate, Microcrystalline Wax, Ceresin, Ozokerite, DiglycerylSebacate/Isopalmitate, Octyldodecanol, Polyglyceryl-2 Triisostearate, Alumina, Dicalcium Phosphate, Iron Oxides (CI 77491), VP/Hexadecene Copolymer, SorbitanIsostearate, Euphorbia Cerifera (Candelilla) Wax, Red 7 (CI 15850:1), Iron Oxides (CI 77492), Polyethylene, PentaerythritylTetraisostearate, Silica Dimethyl Silylate, Polyglyceryl-2 Diisostearate, Mica (CI 77019), Yellow 6 Lake (CI 15985), Tocopheryl Acetate, Iron Oxides (CI 77499), MangiferaIndica (Mango) Seed Butter, ButyrospermumParkii (Shea) Butter, Diamond powder, Water, Butylene Glycol, 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 803 CLASSIC ROSY

titanium dioxide lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60764-054
<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	0.10 g in 3.5 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Diisostearyl Malate</b> (UNII: QBS8 A3XZGQ)	
<b>Triethylhexanoin</b> (UNII: 7K3W1BIU6K)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-054-02	1 in 1 CARTON	08/01/2016	
1	NDC:60764-054-01	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(60764-054)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-054)

Revised: 10/2016

Nanda Co., Ltd