

**3CE LIP COLOR 805 R 19- 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 3.1%

**INACTIVE INGREDIENT**

Inactive Ingredients: Diisostearyl Malate, Triethylhexanoin, EthylhexylHydroxystearate, IsononylIsononanoate, Silica, Microcrystalline Wax, Ceresin, Ozokerite, DiglycerylSebacate/Isopalmitate, Octyldodecanol, Alumina, Red 28 Lake (CI 45410), Polyglyceryl-2 Triisostearate, Dicalcium Phosphate, VP/Hexadecene Copolymer, SorbitanIsostearate, Euphorbia Cerifera (Candelilla) Wax, Mica (CI 77019), Polyglyceryl-2 Diisostearate, Polyethylene, Red 7 (CI 15850:1), PentaerythritylTetraisostearate, Silica Dimethyl Silylate, Yellow 6 Lake (CI 15985), Tocopheryl Acetate, Blue 1 Lake (CI 42090), 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 #805 R 19 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 3.1% INACTIVE INGREDIENTS: Diisostearyl Malate, Triethylhexanoin, Ethylhexylhydroxystearate, Isononylisononanoate, Silica, Microcrystalline Wax, Ceresin, Ozokerite, Diglycerol Sebacate/Isopalmitate, Octyldecanoate, Alumina, Red 28 Lake (C145410), Polyglyceryl-2 Triisostearate, Dicalcium Phosphate, VP1/hexadecene Copolymer/Sorbitan sebacate, Euphorbia Cerifera (Candelilla) Wax, Mea (C177019), Polyglyceryl-2 Diisostearate, Polyethylene, Red7 (C116650.1), Parabenylthio Tetraostearate, Silica Dimethyl Silylate, Yellow 6 Lake (C119263), Tocopheryl Acetate, Blue 1 Lake (C142090), Mangifera indica (Mango) Seed Butter, Butyrospermum Parkii (Shea) Butter, Diamond powder, Water, Butylene Glycol, Amethyst Powder, Pearl Powder, Tourmaline, Methylparaben PURPOSE: Sunscreen CAUTION: 1. Discontinue use and consult a doctor when 1) your skin itches, 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 805 R 19

titanium dioxide lipstick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-056
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	0.10 g in 3.5 g

### Inactive Ingredients

Ingredient Name	Strength
Diisostearyl Malate (UNII: QBS8A3XZGQ)	
Triethylhexanoin (UNII: 7K3W1BIU6K)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-056-02	1 in 1 CARTON	08/01/2016	
1	NDC:60764-056-01	3.5 g in 1 BOTTLE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
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)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Nanda Co., Ltd		557816075	repack(60764-056)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-056)

Revised: 10/2016

Nanda Co., Ltd