

3CE LIP COLOR 804 STAY BY ME- 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.

ACTIVE INGREDIENT

Active Ingredient: Titanium Dioxide 4.3%

INACTIVE INGREDIENT

Inactive Ingredients: Diisostearyl Malate, Triethylhexanoin, EthylhexylHydroxystearate, IsononylIsononanoate, Silica, Microcrystalline Wax, Ceresin, Ozokerite, Polyglyceryl-2 Triisostearate, DiglycerylSebacate/Isopalmitate, Octyldodecanol, Alumina, Dicalcium Phosphate, VP/Hexadecene Copolymer, SorbitanIsostearate, Euphorbia Cerifera (Candelilla) Wax, Yellow 5 Lake (CI 19140), Red 28 Lake (CI 45410), Polyethylene, PentaerythritylTetraisostearate, Silica Dimethyl Silylate, Mica (CI 77019), Polyglyceryl-2 Diisostearate, Red 7 (CI 15850:1), 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 #804 STAY BY ME 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 4.3% INACTIVE INGREDIENTS: Diisostearyl Malate, Triethylhexanoin, Ethylhexyl Hydroxystearate, Isononyl Isononanoate, Silica, Microcrystalline Wax, Ceresin, Ozokerite, Polyglyceryl-2 Trisostearate, Diglycerol Sebacate/Isopalmitate, Octyldodecanol, Alumina, Dicalcium Phosphate, VP-14/Isododecane Copolymer, Sorbitan Isostearate, Euphorbia Cerifera (Candelilla) Wax, Yellow 5 Lake (CI 19140), Red 28 Lake (CI 45410), Polyethylene, Pentaerythrityl Tetraostearate, Silica Dimethyl Silylate, Mica (CI 77019), Polyglyceryl-2 Diostearate, Red 7 (CI 15850-1), Yellow 6 Lake (CI 15780), Tocopheryl Acetate, Iron Oxides (CI 77499), Mangiferalindica (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 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

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titanium dioxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-055
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	0.15 g in 3.5 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-055-02	1 in 1 CARTON	08/01/2016	
1	NDC:60764-055-01	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(60764-055)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-055)

Revised: 10/2016

Nanda Co., Ltd