

3CE LIP COLOR 308 PINK JAM- 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 3.6%

INACTIVE INGREDIENT

Inactive Ingredients: Triethylhexanoin, Diisostearyl Malate, Trimethylolpropane Tricaprylate/Tricaprate, Isononyl Isononanoate, Mica (CI 77019), Polyglyceryl-2 Triisostearate, Diglyceryl Sebacate/Isopalmitate, Silica, Ceresin, Ozokerite, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Pentaerythrityl Tetraisostearate, Red 28 Lake (CI 45410), VP/Hexadecene Copolymer, Polyglyceryl-2 Diisostearate, Microcrystalline Wax, Sorbitan Isostearate, Silica Silylate, Polyethylene, Red 7 (CI 15850:1), Synthetic Wax, Silica Dimethyl Silylate, 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 308 PINK JAM

titanium dioxide lipstick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60764-068 |
| 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 | 0.12 g in 3.5 g |

Inactive Ingredients

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:60764-068-02 | 1 in 1 CARTON | 08/01/2016 | |
| 1 | NDC:60764-068-01 | 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(60764-068) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| Cosmax, Inc. | | 689049693 | manufacture(60764-068) |

Revised: 10/2016

Nanda Co., Ltd