

### **3CE DRAWING LIP PEN ENDEAR- 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 21.0%

#### **INACTIVE INGREDIENT**

Inactive Ingredients: Mica, Hydrogenated Coco-Glycerides, Rhus Succedanea Fruit Wax, Stearic Acid, Yellow 6 Lake (CI 15985), Hydrogenated Castor Oil, Triethylhexanoin, Red 21 Lake (CI 45380), Acetylated Sucrose Distearate, Lanolin, Microcrystalline Wax, Red 7 Lake (CI 15850), Red 6 Lake (CI 15850), Butylparaben

#### **PURPOSE**

Purpose: Sunscreen

#### **CAUTION**

CAUTION: 1. If following problems occur upon using the product, stop use immediately; further use may worsen the symptoms. Consult with a dermatologist if necessary. 1) Red spots, swelling, itchiness, irritation, or any other irregularities. 2) If applied area shows above symptoms when exposed to direct sunlight. 2. Do not use on areas with skin conditions such as open wound, eczema, or any skin disease. 3. Notes on storage and handling 1) Always put the lid back on after use 2) Keep away from reach of children 3) Keep away from high/low temperature or direct sunlight

#### **DESCRIPTION**

INSTRUCTIONS: Pencil-type lipstick that glides on lips like a crayon.

Directions: Hold the pencil flat against the lip and apply by tracing your natural lip line, moving towards to fill in.

#### **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



## 3CE DRAWING LIP PEN ENDEAR

titanium dioxide lipstick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60764-104
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	0.23 g in 1.1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Mica</b> (UNII: V8A1AW0880)	
<b>Triethylhexanoin</b> (UNII: 7K3W1BIU6K)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-104-02	1 in 1 CARTON	08/01/2016	
1	NDC:60764-104-01	1.1 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
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OTC monograph not final	part352	08/01/2016	
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**Labeler** - Nanda Co., Ltd (557816075)

**Registrant** - Nanda Co., Ltd (557816075)

**Establishment**

Name	Address	ID/FEI	Business Operations
Nanda Co., Ltd		557816075	manufacture(60764-104)

Revised: 10/2016

Nanda Co., Ltd