

3CE DRAWING LIP PEN NEED- titanium dioxide lipst tick

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 24.5%

INACTIVE INGREDIENT

Inactive Ingredients: Mica, Hydrogenated Coco-Glycerides, Rhus Succedanea Fruit Wax, Stearic Acid, Triethylhexanoin, Iron Oxides(CI 77492), Hydrogenated Castor Oil, Lanolin, Acetylated Sucrose Distearate, Red 6 (CI 15850), Iron Oxides(CI 77491), Microcrystalline Wax, Iron Oxides(CI 77499), 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 NEED

titanium dioxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-107
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	0.26 g in 1.1 g

Inactive Ingredients

Ingredient Name	Strength
Mica (UNII: V8A1AW0880)	
Stearic Acid (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-107-02	1 in 1 CARTON	08/01/2016	
1	NDC:60764-107-01	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
--------------------	--	----------------------	--------------------

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	manufacture(60764-107)

Revised: 10/2016

Nanda Co., Ltd