# 3CE CRE AMY LIP COLOR 14 LOLLIPOP- 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 4.1%

#### **INACTIVE INGREDIENT**

Inactive Ingredients: Squalane, Caprylic/Capric Triglyceride, Ethylhexyl Hydroxystearate, Butyloctyl Salicylate, Ozokerite, Pentaerythrityl Tetraisostearate, Diisostearyl Malate, Diglyceryl Sebacate/Isopalmitate, Polyethylene, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, Hydrogenated Polyisobutene, Ceresin, Microcrystalline Wax, Red 28 Lake (CI 45410), Polyglyceryl-2 Triisostearate, Dicalcium Phosphate, VP/Eicosene Copolymer, VP/Hexadecene Copolymer, Sorbitan Isostearate, Alumina, Polyglyceryl-2 Diisostearate, Phytosteryl Macadamiate, Glyceryl Caprylate, Caprylyl Glycol, Blue 1 Lake (CI 42090), Argania Spinosa Kernel Oil, Theobroma Grandiflorum Seed Butter

#### **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: Intense moisturizing lip color lipstick that blends into your lips as soon as it is applied.

Directions: After applying a thin layer of lipstick, another layer of clear lip gloss will allow an additional transparency

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



### 3CE CRE AMY LIP COLOR 14 LOLLIPOP

titanium dioxide lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-122
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	0.18 g in 4.5 g	

Inactive Ingredients			
Ingredient Name	Strength		
Squalane (UNII: GW89575KF9)			
Ethylhexyl Hydroxystearate (UNII: B7I80BVV5E)			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:60764-122-02	1 in 1 CARTON	08/10/2016	
1	NDC:60764-122-01	4.5 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	08/10/2016	

### **Labeler -** Nanda Co., Ltd (557816075)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Nanda Co., Ltd		557816075	repack(60764-122)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Cosmax, Inc.		689049693	manufacture(60764-122)	

Revised: 10/2016 Nanda Co., Ltd