

### **3CE CRE AMY LIP COLOR 16 GIDDY UP- 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 2.0%

#### **PURPOSE**

Purpose: Sunscreen

#### **INACTIVE INGREDIENT**

Inactive Ingredients: Squalane, Caprylic/Capric Triglyceride, Ethylhexyl Hydroxystearate, Butyloctyl Salicylate, Ozokerite, Polyglyceryl-2 Triisostearate, Diglyceryl Sebacate/Isopalmitate, VP/Hexadecene Copolymer, Polyethylene, Phytosteryl/Isostearyl/Cetyl/Stearyl/Behenyl Dimer Dilinoleate, Hydrogenated Polyisobutene, Red 28 Lake (CI 45410), Ceresin, Microcrystalline Wax, Diisostearyl Malate, Sorbitan Isostearate, Dicalcium Phosphate, VP/Eicosene Copolymer, Polyglyceryl-2 Diisostearate, Alumina, Red 6 (CI 15850), Phytosteryl Macadamiate, Red 22 Lake (CI 45380), Pentaerythrityl Tetraoisostearate, Yellow 6 Lake (CI 15985), Glyceryl Caprylate, Caprylyl Glycol, Argania Spinosa Kernel Oil, Theobroma Grandiflorum Seed Butter, Yellow 5 Lake (CI 19140)

#### **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**

**쓰리씨이 크리미 립 컬러 3CE creamy lip color**

미끄러지듯 부드럽게 발리는 크리미 립 컬러. 에센스 성분의 다량 함유로 입술을 촉촉하게 보충하며 동시에 우수한 광택감을 부여해 줍니다.

본 제품에 이상이 있을 경우 공정거래위원회 고시 품목별 소비자 분쟁 해결기준에 의해 보상해 드립니다. 소비자 상담실 0502-707-8888

**3CE creamy lip color #16 GIDDY UP**

**FUNCTION:** Lipstick. **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.

**COUNTRY OF MANUFACTURE:** South Korea. **NET Wt.** 4.5g. **ACTIVE INGREDIENT:** Titanium Dioxide 2.0%. **INACTIVE INGREDIENTS:** Squalane, Caprylyl/Capric Trioleate, Ethylhexyl Hydroxystearate, Butyl Acrylate, Octenol, Polyglyceryl-2 Trisostearate, Diglycerol Sebacate/Isododecane, VP/Phosphorane Copolymer, Polyethylene, Phytosteryl/Isocetyl/Cetyl/Stearyl/Behenyl Dimethyl Silylate, Hydrogenated Polyisobutene, Red 28 Lake (CI 45410), Ceresin, Microcrystalline Wax, Disostearyl Malate, Sorbitan Isostearate, Dicalcium Phosphate, VP/Eicosene Copolymer, Polyglyceryl-2 Disostearate, Alumina, Red 6 (CI 15850), Phytosteryl Macadamate, Red 22 Lake (CI 45390), Pentaerythrityl Tetraostearate, Yellow 6 Lake (CI 15780), Glyceryl Caprylate, Caprylyl Glycol, Argania Spinosa Kernel Oil, Theobroma Grandiflorum Seed Butter, Yellow 5 Lake (CI 19140). **PURPOSE:** Sunscreen.

**CAUTION:** 1. Discontinue use and consult a doctor when 1) your skin itches, 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.



**3CE CRE AMY LIP COLOR 16 GIDDY UP**

titanium dioxide lipstick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:60764-124
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	Titanium Dioxide	0.09 g in 4.5 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>Squalane</b> (UNII: GW89575KF9)	
<b>Ethylhexyl Hydroxystearate</b> (UNII: B7I80BVV5E)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-124-02	1 in 1 CARTON	08/10/2016	
1	NDC:60764-124-01	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(60764-124)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-124)

Revised: 10/2016

Nanda Co., Ltd