

**3CE FITTING CUSHION FOUNDATION 001- titanium dioxide, octinoxate, octisalate powder  
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 14.1%, Ethylhexyl Methoxycinnamate 6.7%, Ethylhexyl Salicylate 4.0%

**INACTIVE INGREDIENT**

Inactive Ingredients: Water, Cyclopentasiloxane, Trimethylsiloxysilicate, Butylene Glycol, PEG-8 Dimethicone, Butylene Glycol Dicaprylate/Dicaprate, Diphenylsiloxy Phenyl Trimethicone, Dipropylene Glycol, Niacinamide, Pentylene Glycol, Iron Oxides (CI 77492), C12-15 Alkyl Benzoate, Cetyl PEG/PPG-10/1 Dimethicone, Neopentyl Glycol Diheptanoate, PEG-8, Magnesium Sulfate, Synthetic Fluorphlogopite, Dimethicone, SorbitanIsostearate, Phenoxyethanol, DimethiconeCrosspolymer, DistardimoniumHectorite, Stearic Acid, Alumina, Aluminum Hydroxide, Triethoxycaprylylsilane, Iron Oxides (CI 77491), Fragrance(Parfum), Iron Oxides (CI 77499), Hydrogenated Castor Oil Isostearate, Ethylhexylglycerin, Adenosine, Disodium EDTA, Methyl Methacrylate Crosspolymer, Hydrolyzed Hyaluronic Acid, AnastaticaHierochuntica Extract, Alcohol, AchilleaMillefolium Extract, Arnica Montana Flower Extract, Artemisia Absinthium Extract, GentianaLutea Root Extract, Lactobacillus Ferment, Potassium Sorbate

**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 Cushion compact foundation keeps your face looking perfectly just like the start of the day and prevents further darkening of skin. The lightweight, low-viscosity formula helps the foundation adhere to skin instantly while providing excellent coverage just like a liquid foundation.

Directions: Take a small amount with the Ruby Cell Puff and spread evenly over face Please make sure to close the lid after use.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



3CE fitting cushion foundation #001

FUNCTION: Foundation

INSTRUCTIONS: A cushion compact foundation keeps your face looking perfectly just like the start of the day and prevents further darkening of skin. The lightweight, low-staining formula helps the foundation adhere to skin instantly while providing excellent coverage just like a liquid foundation.

DIRECTIONS: Take a small amount with the Ruby Cell. Puff and spread evenly over face. Please make sure to close the lid after use.

COUNTRY OF MANUFACTURE: South Korea  
NET Wt. 13g/2

ACTIVE INGREDIENT: Titanium Dioxide 14.1%, EthylhexylMethacrylate 7%, Dihexyl Sebacate 0%.  
INACTIVE INGREDIENTS: Water, Cyclopentasiloxane, Trimethylsiloxysilicate, Butylene Glycol, PEG-8 Dimethicone, Butylene Glycol Dicaprylate/Dicaprate, Disubstituted Phenyl Trimethylsilyloxy Dimethylsiloxane, Nonylphenyl Glycidyl Ether Dicaprylate/Dicaprate, Iron Oxide [CI 77492, CI-77:19 Alum. Silicate, Cetyl PEG/PPG-10/1 Dimethylsiloxane, Carbonyl Diisobutyrate, Dimethylsiloxane, Silica, Synthetic Fluorphlogopite, Dimethicone, Carbonyl Diisobutyrate, Phenylethanol, Dimethylsilyloxydimethylsiloxane, Octadecyltrimethylammonium Chloride, Acrylic Acid, Aluminum, Aluminum Hydroxide, Triethoxypropyl Siloxane Iron Oxide [CI 77491], Fragrance/Parfum, Iron Oxide [CI 77491], Hydrogenated Castor Oil, Isostearamide, Ethylhexylglycerin, Adenosine, Quindim 0276, Methyl Methacrylate Crosspolymer, Hydrolyzed Hyaluronic Acid, Anacardic acid/Anacardic Extract, Alcohol, AchilleaMillefolium Extract, Arnica Montana Flower Extract, Artemisia Absinthium Extract, Geraniol/Jamaica Rose Extract, Lactobacillus Ferment, Potassium Sorbate

PURPOSE: Sunscreen

CAUTION: 1. Discontinue use and consult a doctor when 1) your skin irritates, swells, itches, shows spots or areas applied 2) your skin reacts similarly with above when exposed to sunlight 2. Avoid applying on wounded, irritated, cracked 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.



100 #

## 3CE FITTING CUSHION FOUNDATION 001

titanium dioxide, octinoxate, octisalate powder

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-131
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	1.69 g in 12 g
Octinoxate (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	0.80 g in 12 g
Octisalate (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	Octisalate	0.48 g in 12 g

### Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0 KO0R)	
Butylene Glycol (UNII: 3XUS85K0 RA)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-131-02	2 in 1 CARTON	08/10/2016	
1	NDC:60764-131-01	12 g in 1 CONTAINER; 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(60764-131)

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(60764-131)

Revised: 10/2016

Nanda Co., Ltd