

**3CE TINTED MOISTURE CUSHION CC 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 8.9%, Ethylhexyl Methoxycinnamate 6.7%, Ethylhexyl Salicylate 4.0%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Cyclopentasiloxane, Cyclohexasiloxane, Dimethicone, Butylene Glycol, Butylene Glycol Dicaprylate/Dicaprate, PEG-8 Dimethicone, Glycerin, Niacinamide, Pentylene Glycol, Trimethylsiloxysilicate, Methyl Methacrylate Crosspolymer, Neopentyl Glycol Diheptanoate, Dimethicone/Vinyl Dimethicone Crosspolymer, Diphenylsiloxy Phenyl Trimethicone, Cetyl PEG/PPG-10/1 Dimethicone, PEG-8, Iron Oxides (CI 77492), Magnesium Sulfate, Disteardimonium Hectorite, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Sorbitan Isostearate, Phenoxyethanol, Mica (CI 77019), Stearic Acid, Alumina, Fragrance (Parfum), Iron Oxides (CI 77491), Dimethicone Crosspolymer, Triethoxycaprylylsilane, Ethylhexylglycerin, Iron Oxides (CI 77499), Adenosine, Disodium EDTA, Hydrogenated Castor Oil Isostearate, Hydrolyzed Hyaluronic Acid, Anastatica Hierochuntica Extract, Alcohol, Gentiana Lutea Root Extract, Achillea Millefolium Extract, Artemisia Absinthium Extract, Arnica Montana Flower 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 exposure to sunlight, high and low temperatures

DESCRIPTION

INSTRUCTIONS: Layering Cushion CC covers face moisture as if it has done treatment. 3CE Tinted Moisture Cushion CC creates a moisture layer with a hydrating complex for dewy radiance.

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 TINTED MOISTURE CUSHION CC 001

titanium dioxide, octinoxate, octisalate powder

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60764-129 |
| 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 | 1.06 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) | |

Dimethicone (UNII: 92RU3N3Y1O)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:60764-129-02 | 2 in 1 CARTON | 08/10/2016 | |
| 1 | NDC:60764-129-01 | 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(60764-129) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| Cosmax, Inc. | | 689049693 | manufacture(60764-129) |

Revised: 10/2016

Nanda Co., Ltd