

**3 CONCEPT EYES BACK TO BABY- titanium dioxide, octinoxate cream
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 ingredients: Titanium Dioxide 9.694%, Ethylhexyl Methoxycinnamate 5.000%

INACTIVE INGREDIENT

Inactive ingredients: Water, Cyclopentasiloxane, Butylene Glycol, Phenyl Trimethicone, Dicaprylyl Carbonate, Butylene Glycol Dicaprylate/Dicaprate, PEG-10 Dimethicone, Zinc Oxide (CI 77947), Niacinamide, Sodium Chloride, Cyclomethicone, Glycerin, Disteardimonium Hectorite, Pentylene Glycol, Iron Oxides (CI 77492), Glyceryl Behenate/Eicosadioate, Sorbitan Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Trimethylsiloxysilicate, Methyl Methacrylate Crosspolymer, Phenoxyethanol, Dimethicone Crosspolymer, Iron Oxides (CI 77491), Aluminum Hydroxide, Stearic Acid, Iron Oxides (CI 77499), Triethoxycaprylylsilane, Fragrance (Parfum), Acrylates/Dimethicone Copolymer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Adenosine, Sodium Hyaluronate, Pearl Powder, Amethyst Powder, Tourmaline, Diamond powder, Coral Powder, Portulaca Oleracea Extract, Methylparaben

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings:

Keep out of eyes.

Stop use if irritation occurs.

Keep out of reach of babies and children.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of babies and children.

INDICATIONS AND USAGE

Indication and usage:

1. Always recap after use.

2. Store this product at room temperature.

DOSAGE AND ADMINISTRATION

Dosage and administration:

Put suitable amount of contents on the sponge or brush and then apply from inside your face evenly.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



3 CONCEPT EYES BACK TO BABY

titanium dioxide, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60764-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	2.90 mg in 30 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Butylene Glycol (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60764-011-01	30 mL in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2013	

Labeler - NANDA CO., LTD. (557816075)

Registrant - NANDA CO., LTD. (557816075)

Establishment

Name	Address	ID/FEI	Business Operations
NANDA CO., LTD.		557816075	manufacture(60764-011)

Revised: 2/2014

NANDA CO., LTD.