

**PROVENCE TWO WAY PACT SPF50PLUS PA PLUS PLUS PLUS 02 NATURAL BEIGE-titanium dioxide, octinoxate, zinc oxide powder
NATURE REPUBLIC 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 11.64%, Ethylhexyl Methoxycinnamate 6%, Zinc Oxide 2.94%

INACTIVE INGREDIENT

Inactive Ingredients:

Talc, Synthetic Fluorophlogopite, Mica (CI 77019), Barium Sulfate, Silica, Dimethicone, Boron Nitride, Alumina, HDI/Trimethylol Hexyllactone Crosspolymer, Iron Oxides (CI 77492), Methicone, Magnesium Myristate, Methyl Methacrylate Crosspolymer, Dipentaerythryl Hexahydroxystearate/Hexastearate/Hexarosinate, Ethylhexylglycerin, Glyceryl Caprylate, Iron Oxides (CI 77491), Fragrance(Parfum), Iron Oxides (CI 77499), Acrylates/Tridecyl Acrylate/Triethoxysilylpropyl Methacrylate/Dimethicone Methacrylate Copolymer, Triethoxycaprylylsilane, Rosmarinus Officinalis (Rosemary) Leaf Extract, Rosa Canina Fruit Oil

PURPOSE

PURPOSE: Sunscreen

WARNINGS

Cautions:

For external use only.

Avoid contact with eyes and mouth.

Discontinue use if signs of irritation or rashes appear.

Keep out of reach of children.

Replace the cap after use.

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

INDICATIONS AND USAGE

How to Use: Apply an appropriate amount to the skin evenly.

DOSAGE AND ADMINISTRATION

How to Use: Apply an appropriate amount to the skin evenly.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



PROVENCE TWO WAY PACT SPF50PLUS PA PLUS PLUS PLUS 02 NATURAL BEIGE
 titanium dioxide, octinoxate, zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51346-207
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	1.39 g in 12 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.72 g in 12 g
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.35 g in 12 g

Inactive Ingredients	
Ingredient Name	Strength

TALC (UNII: 7SEV7J4R1U)

Dimethicone (UNII: 92RU3N3Y1O)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51346-207-01	12 g in 1 CARTON; Type 0: Not a Combination Product	02/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2013	

Labeler - NATURE REPUBLIC CO., LTD. (631172020)

Registrant - NATURE REPUBLIC CO., LTD. (631172020)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmax, Inc.		689049693	manufacture(51346-207)

Revised: 12/2019

NATURE REPUBLIC CO., LTD.