RED ORANGE SUN PACT SPF 50 PLUS PA PLUS PLUS PLUS- octinoxate powder SKINFOOD 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.

Drug Facts

Active ingredients: OCTINOXATE 7%, TITANIUM DIOXIDE 3.104%, ZINC OXIDE 2.88%

Inactive ingredients:

Talc, Mica (CI 77019), Methyl Methacrylate Crosspolymer, Silica, Nylon-12, Ethylene/Acrylic Acid Copolymer, Methylene Bis-Benzotriazolyl Tetramethylbutylpheno, Trimethylolpropane Triethylhexanoate, Phenyl Trimethicone, Magnesium Myristate, Dimethicone, Aluminum Hydroxide, Methylparaben, MethiconeDimethicone/Methicone Copolymer, Iron Oxides (CI 77491), Iron Oxides (CI 77492), Fragrance(Parfum), Propylparaben, Iron Oxides (CI 77499), Citrus Aurantium Dulcis (Orange) Fruit Extract, Caprylic/Capric Triglyceride, Solanum Lycopersicum (Tomato) Fruit Oil, Water

Purpose: Protects skin from UV rays.

Warnings:

For external use only.

Avoid contact with eyes.

Discontinue use if signs of irritation appear.

Keep out of reach of children:

Keep out of reach of children.

Indication and usage:

Using the enclosed puff, apply evenly onto the entire face.

Dosage and administration:

Give a smooth tapping massage around your skin with the enclosed puff, and reapply to areas which produce sebum secretion as often as possible to give a fresh finish.



Dosage and administration: Give a smooth tapping massage around your skin with the enclosed puff, and reapply to areas which produce sebum secretion as often as possible to give a fresh finish

Indication and usage: Using the enclosed puff, apply evenly onto the entire face. Purpose:Protects skin from UV rays Warning: Keep out of reach of children. For external use only. Avoid contact with eyes. Discontinue use if signs of irritation appear.

Dist. SKINFOOD USA, INC. 1 Technology Drive, Bldg. B, Suite B113 Irvine, California, 92618 www.theskinfood.com octinoxate powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76214-037
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.66 g in 9.5 g	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM - UNII:D1JT6 11TNE)	TITANIUM DIO XIDE	0.29 g in 9.5 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC OXIDE	0.27 g in 9.5 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TALC (UNII: 7SEV7J4R1U)	
MICA (UNII: V8A1AW0880)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
TRIMETHYLOLPROPANE TRIETHYLHEXANO ATE (UNII: B952ZGW1IL)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NO J4R)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ORANGE (UNII: 5EVU04N5QU)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TOMATO (UNII: Z4KHF2C175)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76214-037-01	9.5 g in 1 CARTON		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2011	

Labeler - SKINFOOD CO., LTD. (690324173)

Registrant - SKINFOOD CO., LTD. (690324173)

Establishment				
Name	Address	ID/FEI	Business Operations	
SKINFOOD CO., LTD.		690324173	manufacture	

Revised: 10/2011 SKINFOOD CO., LTD.