RED ORANGE SUN SPF 45 PA PLUS PLUS PLUS- titanium dioxide 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: TITANIUM DIOXIDE 13.937%, ZINC OXIDE 2.94%

Inactive ingredients:

Talc, Mica (CI 77019), Silica, Aluminum Starch Octenylsuccinate, Dimethicone, Ethylhexyl Methoxycinnamate, Methicone, Iron Oxides (CI 77492), Triethoxycaprylylsilane, Citrus Aurantium Dulcis (Orange) Peel Oil, Iron Oxides (CI 77491), Aluminum Hydroxide, Methylparaben, Iron Oxides (CI 77499), Propylparaben

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:

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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.



RED ORANGE SUN SPF 45 PA PLUS PLUS titanium dioxide powder Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration CUTANEOUS

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM - UNII:D1JT611TNE)	TITANIUM DIO XIDE	2.79 g in 20 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC OXIDE	0.59 g in 20 g	

Inactive Ingredients	
Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
MICA (UNII: V8A1AW0880)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
ALUMINUM STARCH O CTENYLSUCCINATE (UNII: 19PJ0 O 6 2 9 4)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
OCTINOXATE (UNII: 4Y5P7MUD51)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
ORANGE (UNII: 5EVU04N5QU)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:76214-038-01	20 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.