

FACE IT 4D PERFECTION ROLLER FOUNDATION 21 - octinoxate, titanium dioxide cream
THEFACESHOP 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

OCTINOXATE (3%)

TITANIUM DIOXIDE (23.51%)

TRIETHOXYCAPRYLYLSILANE

WATER

ISONONYL ISONONANOATE

DICAPRYLYL CARBONATE

PHENYL TRIMETHICONE

DIMETHICONE

SILICON DIOXIDE

MINERAL OIL

CALCIUM CARBONATE

HIGH DENSITY POLYETHYLENE

FERRIC OXIDE RED

CARNAUBA WAX

CANDELILLA WAX

MICROCRYSTALLINE WAX

TRIBEHENIN

HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW)

BUTYLENE GLYCOL

CHAMAEMELUM NOBILE FLOWER

GINGER

Provides high protection against sunburn and tanning.

Avoid contact with eyes.

Discontinue use if sign of irritation or rash appear.

Dispense an adequate amount and apply evenly. (At the final stage of basic skincare, dispense an adequate amount and apply evenly to desired parts)

FACE IT 4D PERFECTION ROLLER FOUNDATION NB 21



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octinoxate, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51523-109
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 g in 100 g

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)

TITANIUM DIOXIDE

23.51 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MINERAL OIL (UNII: T5L8T28FGP)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CANDELILLA WAX (UNII: WL0328HX19)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
GINGER (UNII: C5529G5J PQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51523-109-02	1 in 1 BOX		
1	NDC:51523-109-01	8 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2011	

Labeler - THEFACESHOP CO., LTD (688329416)**Registrant** - THEFACESHOP CO., LTD (688329416)**Establishment**

Name	Address	ID/FEI	Business Operations
THEFACESHOP CO., LTD		688329416	manufacture