

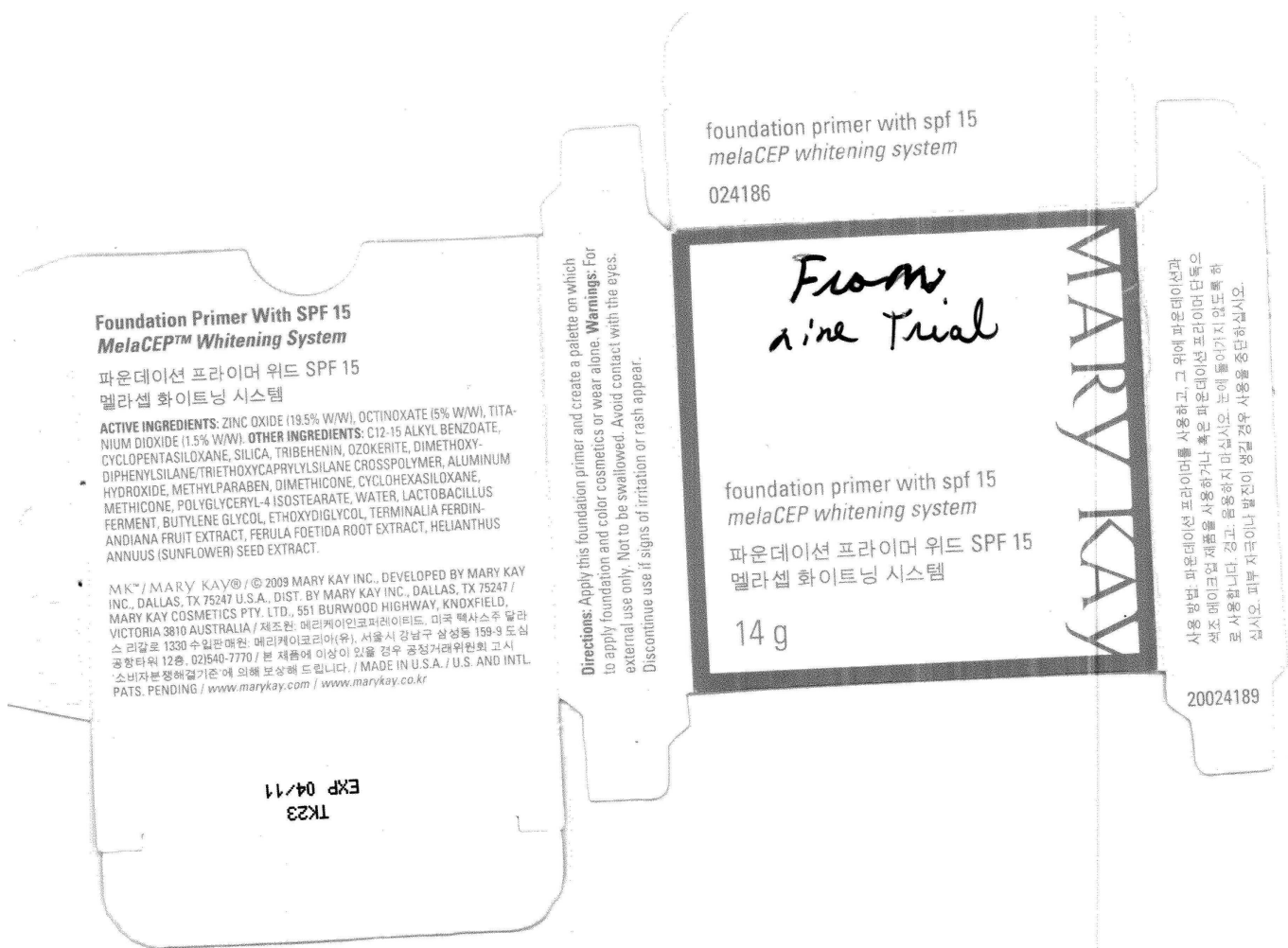
FOUNDATION PRIMER SPF 15 - titanium dioxide , zinc oxide , octinoxate cream
Mary Kay Inc.

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 INGREDIENTS: ZINC OXIDE (19.5% W/W), OCTINOXATE(5% W/W) , TITANIUM DIOXIDE (1.5% W/W)

Warnings; Contains OXYBENZONE. For external use only. Not to be swallowed. Avoid contact with the eyes. Discontinue use if signs of irritation or rash appear.

Directions; In the morning , after applying Essence , apply Day Moisturizer With SPF 15 liberally over face and neck.



FOUNDATION PRIMER SPF 15
 titanium dioxide , zinc oxide , octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51531-4189
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.222 g in 14 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2.73 g in 14 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.7 g in 14 g

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
Tribehenin (UNII: 8OC9U7TQZ0)	
CERESIN (UNII: Q1LS2UJO3A)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Methylparaben (UNII: A218C7HI9T)	
Dimethicone (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
Polyglyceryl-4 Isostearate (UNII: 820DPX33S7)	
Water (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
FRUIT (UNII: C2AIY4ERZC)	
FERULA ASSA-FOETIDA ROOT (UNII: 3U9288P88T)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51531-4189-0	14 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/11/2009	

Labeler - Mary Kay Inc. (103978839)