

SUPERNATURAL PORELESS FLAWLESS TINTED SPF 15 - octisalate and titanium dioxide cream

Philosophy, 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.

Drug Facts

Active ingredients

Octisalate 5% w/w

Titanium Dioxide 4% w/w

Cyclopentasiloxane 74.863% w/w

Dimethicone Crosspolymer 6.25% w/w

Dimethicone Vinyl Dimethicone crosspolymer 5.309% w/w

Grossypium Herbaceum Cotton 1.48% w/w

Phytosterols 0.037% w/w

Tocotrienols 0.0160% w/w

Tocopherol 0.0170% w/w

Squalene 0.0150% w/w

Oryza Sativa (Rice) Bran Wax 0.0150% w/w

Retinyl Palmitate 0.100% w/w

Simethicone 0.0025% w/w

Alumina 0.0025% w/w

Dimethicone 0.2400% w/w

Silica 0.400% w/w

Squalane 0.200% w/w

Fragrance 0.1000% w/w

Triethoxycaprylylsilane 0.0045% w/w

Phenoxyethanol 0.2750% w/w

Caprylyl Glycol 0.2250% w/w

Iron Oxides 0.4485% w/w

STOP USE AND ASK DOCTOR IF RASH OR IRRITATION DEVELOPS AND LASTS

WARNINGS: FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT:

KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE.

KEEP OUT OF REACH OF CHILDREN.

IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CENTER RIGHT AWAY.

INDICATIONS:

HELPS PREVENT SUNBURN

HIGHER SPF GIVES MORE SUNBURN PROTECTION

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DIRECTIONS: APPLY EVENLY OVER ENTIRE FACE AS A FOUNDATION OR PRIMER OR ALONE. APPLY LIBERALLY BEFORE SUN EXPOSURE AND AS NEEDED.

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50184-3800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	40 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Levant Cotton Oil (UNII: N5CFT140R8)	
.Beta.-Sitosterol (UNII: S347WMO6M4)	
Alpha-Tocopherol (UNII: H4N855PNZ1)	
Squalene (UNII: 7QWM220FJH)	
Rice Germ Oil (UNII: D4H5GGS5JF)	
Vitamin A Palmitate (UNII: 1D1K0N0VVC)	
Aluminum Oxide (UNII: LMI26O6933)	
Dimethicone (UNII: 92RU3N3Y1O)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Squalane (UNII: GW89575KF9)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Ferric Oxide Red (UNII: 1K09F3G675)	
Ferric Oxide Yellow (UNII: EX438O2MRT)	
Ferrosoferric Oxide (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50184-3800-2	1 in 1 CARTON	12/01/2009	
1	NDC:50184-3800-1	45.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2009	

Labeler - Philosophy, Inc. (948102256)

Establishment

Name	Address	ID/FEI	Business Operations
Process Technologies and Packaging Inc.		809172885	manufacture(50 184-3800)

Revised: 1/2010

Philosophy, Inc.