

**SHELTER - octinoxate and octisalate and oxybenzone 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.

Active Ingredients

Octinoxate.....7.5%

Octisalate.....5.0%

Oxybenzone..... 5.0%

Titanium Dioxide.....1.2%

Inactive Ingredients

water (aqua), c12-15 alkyl benzoate, cyclopentasiloxane, glycerin, steareth-21, dimethicone, methyl methacrylate/glycol dimethacrylate crosspolymer, behenyl alcohol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, dimethicone crosspolymer, steareth-2, retinyl palmitate, phytosterols, tocotrienols, tocopherol, squalene, oryza sativa (rice) bran wax, palmitoyl oligopeptide, palmitoyl tetrapeptide-7, rubus fruticosus (blackberry) leaf extract, melanin, lavandula angustifolia (lavender) oil, aloe barbadensis leaf juice, maltodextrin, carbomer, butylene glycol, polysorbate 20, simethicone, alumina, sorbitan laurate, quercetin, diethylhexyl syringylidene malonate, capric caprylic triglycerides, disodium edta, chlorphenesin, phenoxyethanol.

Stop Use

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

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

WHEN USING

WHEN USING THIS PRODUCT KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE.

INDICATIONS

HELPS PREVENT SUNBURN. HIGHER SPF GIVES MORE SUNBURN PROTECTION

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 184-4800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	50 mg in 1 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium - UNII:D1JT611TNE)	Titanium Dioxide	12 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50 184-4800-2	1 in 1 BOX		
1	NDC:50 184-4800-1	56.7 g in 1 TUBE		
2	NDC:50 184-4800-4	1 in 1 BOX		
2	NDC:50 184-4800-3	113.4 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/14/2004	

Labeler - Philosophy, Inc. (948102256)

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Philosophy, Inc.