SPF 50 STAY PUT SUNSCREEN- octinoxate, octisalate, oxybenzone, titanium dioxide lotion Sawyer Products

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.

SPF 50 Stay Put Sunscreen

Drug Facts

Active ingredients:

Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 6.0%, Titanium Dioxide 2.6%

Purpose:

Sunscreen

Uses:

· Helps prevent sunburn.

Warnings:

Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

· For external use only.

Do not use

on broken or damaged skin.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

When using this product

keep out of eyes. Rinse with warm water to remove.

Stop use and ask a doctor

if rash occurs.

Directions:

- · Apply liberally to cool, dry skin 15 minutes before sun exposure.
- · Use a water resistant sunscreen if swimming or sweating.
- · Reapply at least every 2 hours.
- · For children under 6 months of age: ask a doctor before using.

Other information:

· Protect this product container from excessive heat and direct sun.

Inactive ingredients:

Aloe Barbadensis Leaf Juice, Dicaprylyl Maleate, Neopentyl Glycol Diethylhexanoate (and) Neopentyl Glycol Diisostearate, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Phenoxyethanol (and) Methyl paraben (and) Ethylparaben (and) Butylparaben (and)

Propyl paraben (and) Isobutylparaben, Poly ethylene, Poly quaternium 37 (and) Propylene Glycol Dicaprylate/Dicaprate (and) PPG-1 Trideceth-6, Water

Package Labeling:

SAWYER® STAY PUT® SUNSCREEN

This formula is excellent as a touch up to areas such as your ears, nose, tops of feet or shoulders as your traditional sunscreens wear off.

This formula is made heavier by the addition of Titanium Dioxide and goes on differently than most lotions. If you are in a hot environment a full body application may not feel comfortable. Proper application is important. Apply a small amount then spread out evenly. Repeat this process on all exposed skin.

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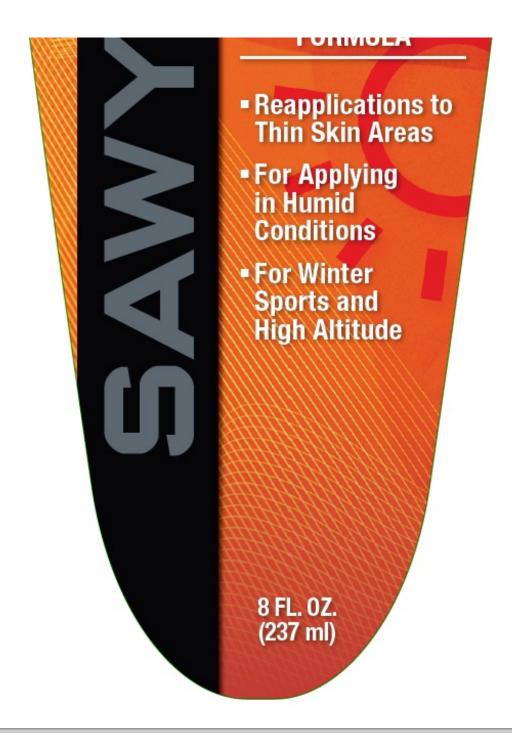
Aloe Barbadensis Leaf Juice, Dicaprylyl Maleate, Neopentyl Glycol Diethylhexanoate (and) Neopentyl Glycol Diisostearate, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Phenoxyethanol (and) Methylparaben (and) Ethylparaben (and) Butylparaben (and) Propylparaben (and) Isobutylparaben, Polyethylene, Polyquaternium 37 (and) Propylene Glycol Dicaprylate/Dicaprate (and) PPG-1 Trideceth-6. Water

> ltem # SP1298 Distributed by: Sawyer Products, Inc. P.O. Box 188, Safety Harbor, FL 34695 www.sawyer.com 800-356-7811



SPF 50





SPF 50 STAY PUT SUNSCREEN

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70392-015	
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 mL		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 mL		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	60 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
DIO CTYL MALEATE (UNII: OD88G8439L)		
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)		
NEOPENTYL GLYCOL DIISOSTEARATE (UNII: 4M6 OQ34JWW)		
O CTYLDO DECYL NEO PENTANO ATE (UNII: X8725R883T)		
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)		
PHENO XYETHANOL (UNII: HIE492ZZ3T)		
METHYLPARABEN (UNII: A218 C7H19 T)		
ETHYLPARABEN (UNII: 14255EXE39)		
BUTYLPARABEN (UNII: 3QPI1U3FV8)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)		
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)		
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)		
WATER (UNII: 059QF0KO0R)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:70392-015-01	1 in 1 CARTON			
1	237 mL in 1 BOTTLE; 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	0 1/15/20 16		

Labeler - Sawyer Products (118285923)

Sawyer Products Revised: 1/2016