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.

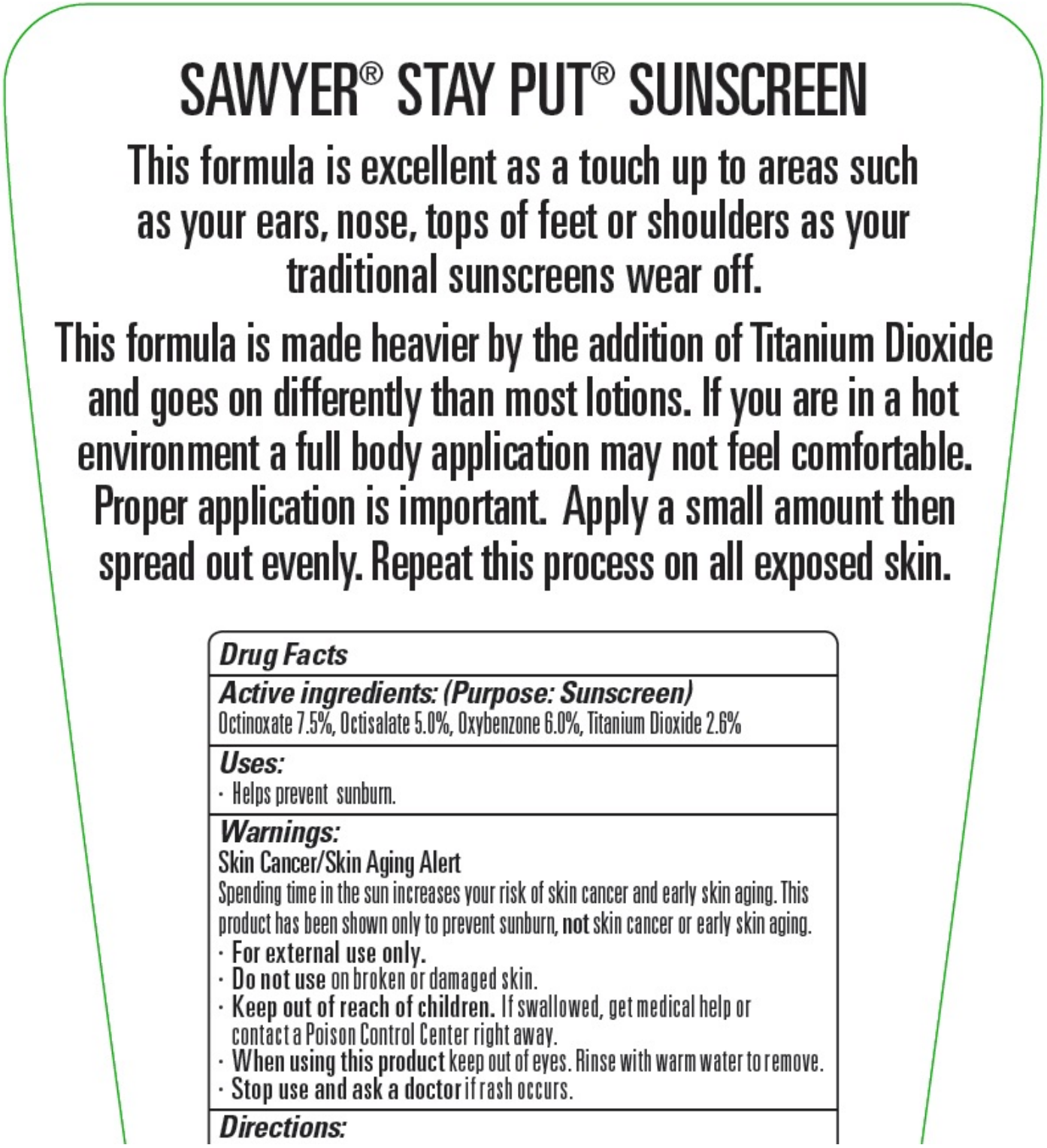
Other information:

· 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) Methylparaben (and) Ethylparaben (and) Butylparaben (and) Propylparaben (and) Isobutylparaben, Polyethylene, Polyquaternium 37 (and) Propylene Glycol Dicaprylate/Dicaprate (and) PPG-1 Trideceth-6, Water

Package Labeling:



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Item # SP1298 Distributed by: Sawyer Products, Inc.
P.O. Box 188, Safety Harbor, FL 34695
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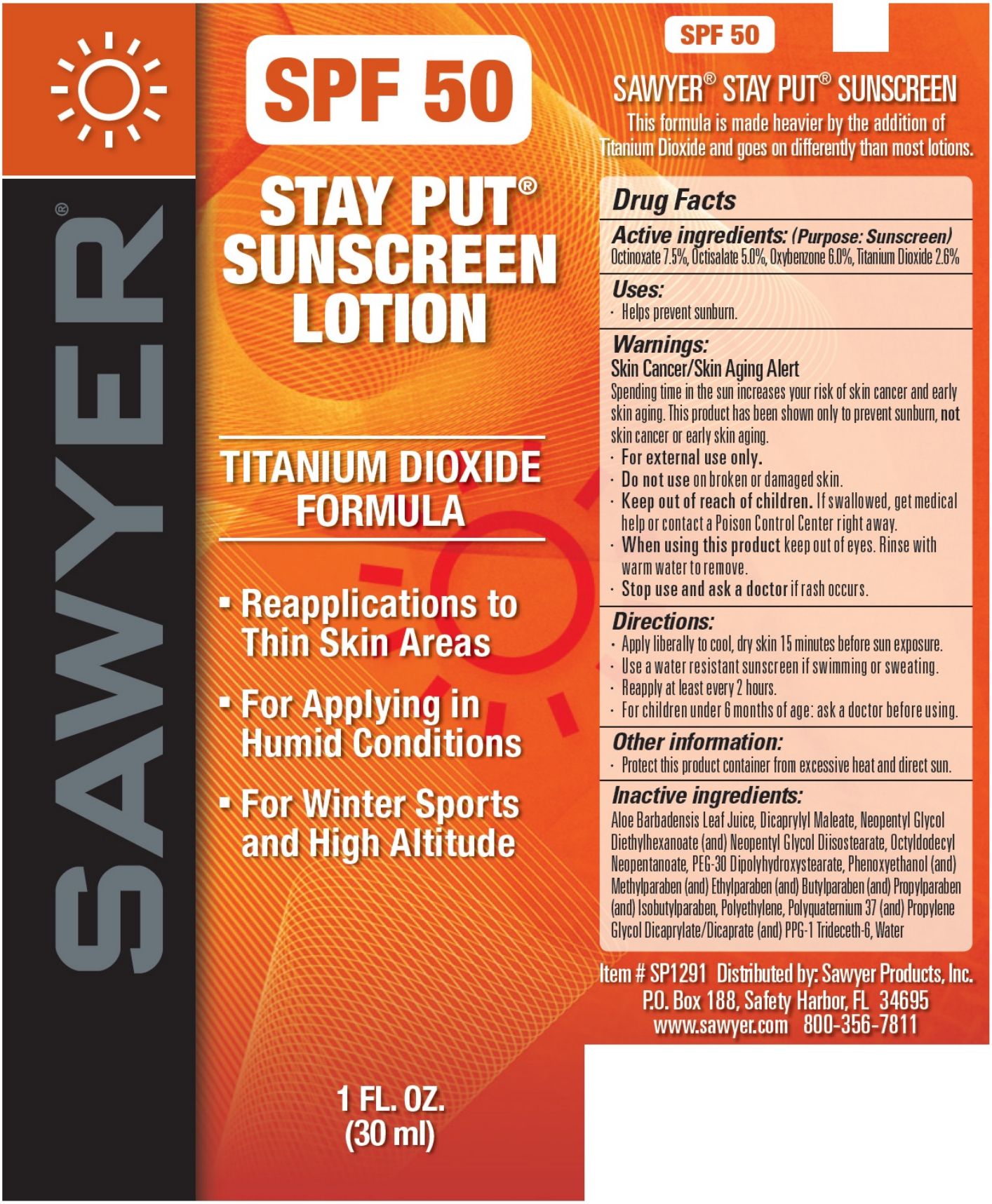
SPF 50



SPF 50 STAY PUT SUNSCREEN

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

Product Information			

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70392-013
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	26 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIOCTYL MALEATE (UNII: OD88G8439L)	
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
NEOPENTYL GLYCOL DIISOSTEARATE (UNII: 4M6OQ34JWW)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)	
PROPYLENE GLYCOL DICAPRATE (UNII: U783H9JHWY)	
PPG-1 TRIDECETH-6 (UNII: 1K7417JX6Q)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70392-013-01	1 in 1 CARTON		
1		30 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	01/15/2016	

Labeler - Sawyer Products (118285923)

Revised: 1/2016 Sawyer Products