

SPF 30 STAY PUT SUNSCREEN- homosalate, octinoxate, octisalate, oxybenzone 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 30 Stay Put Sunscreen Lotion

Drug Facts

Active ingredients:

Homosalate 10.0%, Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 4.0%

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:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Carbomer, Cetyl Alcohol, DEA-Cetyl Phosphate, DMDM Hydantoin (and) Iodopropynyl Butylcarbamate, Hydrogenated Polyisobutene, Stearic Acid, Triethanolamine, Water.

Package Labeling:



SAWYER® STAY PUT® SUNSCREEN—SPF 30

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Item # SP1302 Distributed by:
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SPF 30 STAY PUT SUNSCREEN

homosalate, octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70392-011

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
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	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
IODOPROPYNYL BUTYL CARBAMATE (UNII: 603P14DHEB)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70392-011-01	1 in 1 CARTON		
1		59 mL 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	01/15/2016	

Labeler - Sawyer Products (118285923)

Revised: 1/2016

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