SPF 30 SUNSCREEN- octinoxate, octisalate, oxybenzone, titanium dioxide spray, suspension
Tekweld Solutions, 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.

SPF 30 Sunscreen Spray

Drug Facts

Active Ingredients

Octinoxate 7.5%,

Octisalate 5.0%,

Oxybenzone 2.0%

Titanium Dioxide 2.5%

Soybean oil 3%

Purpose

Sunscreen

Uses

• Helps prevent sunburn

WARNINGS:

Skin Cancer/Skin Aging Alert: Spending time in the sun increase your risk of skin cancer and early skin aging.
This products has been shown only to prevent sunburn, not skin cancer or early skin aging.

For external use only.

Do not use

on damaged or broken skin.

When using this product

keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

if rash occurs.

Keep out of reach of children.

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

Directions

Apply generously & evenly before sun exposure.Reapply as needed or after towel drying, swimming, or sweating. Ask doctor before using on children under 6 months.

Other information

Protect this product from excessive heat and direct sun

Insect Repellent Active Ingredient: Soybean oil 3%
Inactive ingredients

Water, Microcrystalline cellulose, C12-15 Alkyl Benzoate, Isooctyl Palmitate, Propylene Glycol, Glyceryl Stearate Citrate, Disodium EDTA, Iodopropynyl Butylcarbamate, DMDM Hydantoin, Fragrance.

Drug Questions:

877-254-2281

Distributed By:

Tekweld: 45 Rabro Drive, Hauppauge, NY11788

Package Labeling:

Sunscreen SPF 30 0.33 oz / 10 ml

Drug Facts **SPF 30 SUNSCREEN**	***Drug Facts (continued)***
Active Ingredients ***Purpose*** Octinoxate 7.5%. Octisalate 5.0%, Oxybenzone 2.0%, Titanium Dioxide 2.5%.....Sunscreen	***Directions:*** Apply generously & evenly before sun exposure. Reapply as needed or after towel drying, swimming, or sweating. Ask doctor before using on children under 6 months.
Uses: Helps prevent sunburn.	***Other Information:*** Protect this product from excessive heat and direct sun.
***Warnings*: Skin Cancer/Skin Aging Alert**, Spending time in the sun increase your risk of skin cancer and early skin aging. This products has been shown only to prevent sunburn, not skin cancer or early skin aging. **For external use only.** Do not use on damaged or broken skin. When using this product keep out of eyes, rinse with water to remove. Stop use and ask a doctor if rash occurs keep out of reach of children, if product is swallowed, get medical help or contact a poison control center right away.	***Inactive Ingredients*** Water, Microcrystalline cellulose, C12-15 Alkyl Benzoate, Isooctyl Palmitate. Propylene Glycol, Glyceryl Stearate Citrate, Disodium EDTA, IodopropynylButylcarbamate, DMDM Hydantoin, Fragrance. **Drug Questions**: 877-254-2281 **Distributed By**: Tekweld: 45 Rabro Drive, Hauppauge, NY 11788 Made in China

SPF 30 SUNSCREEN

octinoxate, octisalate, oxybenzone, titanium dioxide spray, suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71160-011
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	20 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	25 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOCETYL PALMITATE (UNII: 355356620Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71160-011-00	10 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/22/2017	

Labeler - Tekweld Solutions, Inc. (029077754)

Revised: 12/2019 Tekweld Solutions, Inc.