SPF 30 SUNSCREEN- octinoxate, octisalate, oxybenzone, titanium dioxide lotion
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 lotion

Drug Facts

Active Ingredients

Octinoxate 7.5%,

Octisalate 2.0%,

Oxybenzone 4.0%

Titanium Dioxide 2.5%

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.

Inactive ingredients

Water, Cetearyl Alcohol, Xanthan Gum, C12-15 Alkyl Benzoate, Myristyl Propionate, Propylene Glycol, Glyceryl Stearate Citrate, Disodium EDTA, Iodopropynyl Butylcarbamate, DMDM Hydantoin, Fragrance.

Other information

Protect this product from excessive heat and direct sun

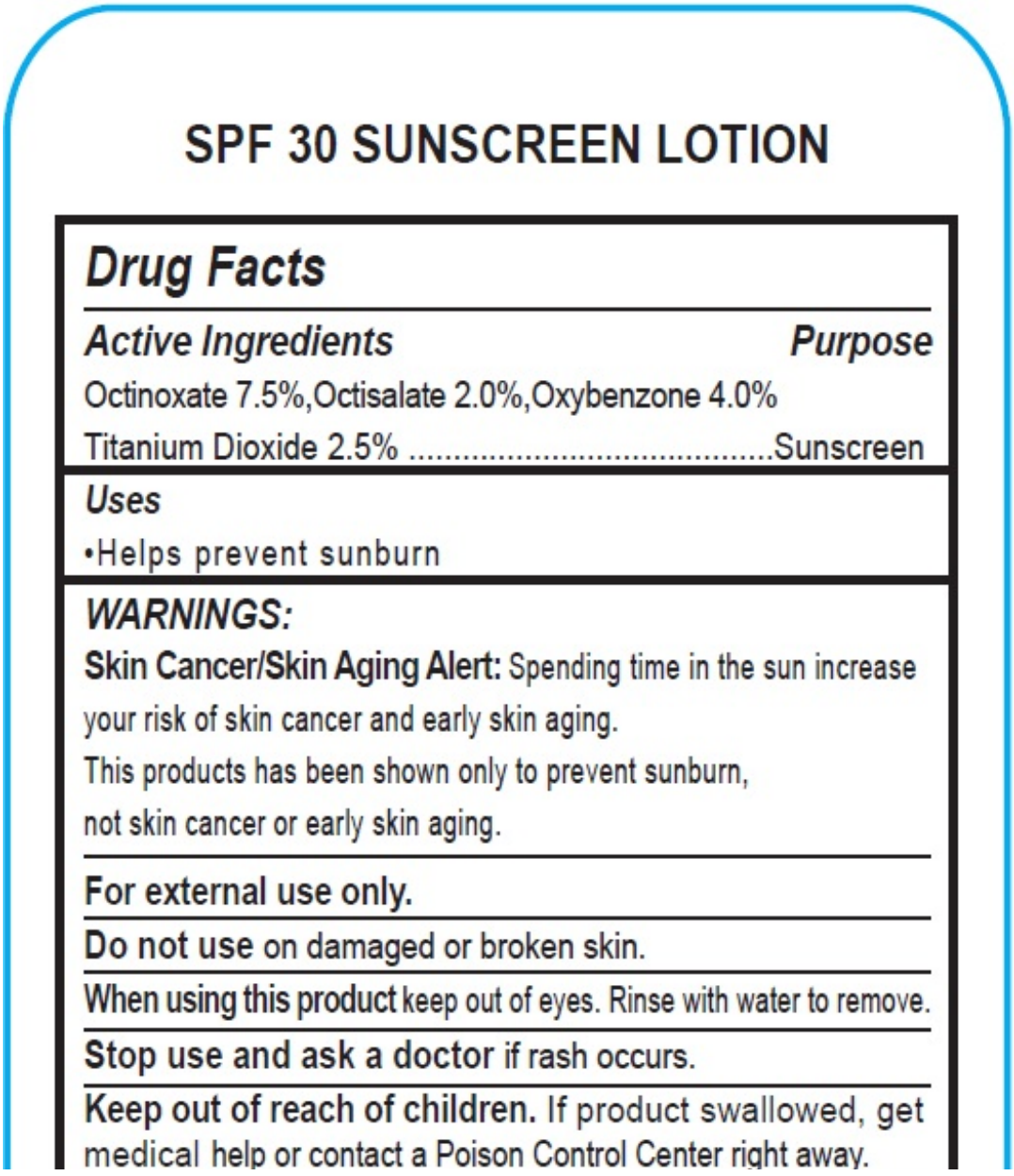
Drug Questions:

877-254-2281

Distributed By:

Tekweld: 45 Rabro Drive, Hauppauge, NY11788

Package Labeling:



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Made in China

SPF 30 SUNSCREEN

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71160-012
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	20 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 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)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

MYRISTYL PROPIONATE (UNII: P59053E7NJ)	
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:71160-012-00	30 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.