

**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.*

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**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:**

**SPF 30 SUNSCREEN LOTION**

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Made in China

**SPF 30 SUNSCREEN**

octinoxate, octisalate, oxybenzone, titanium dioxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71160-013
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	20 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	40 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	25 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>ALKYL (C12-15) BENZOATE</b> (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:71160-013-00	60 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.