

**SPF 30 SUNSCREEN WITH SOYBEAN- 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.*

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**SPF 30 Sunscreen Spray with Soybean Oil**

***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**

<b>Drug Facts</b>	<b>SPF 30 SUNSCREEN</b>	<b>Drug Facts (continued)</b>
<b>Active Ingredients</b> Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 2.0%, Titanium Dioxide 2.5%.....Sunscreen	<b>Purpose</b> Sunscreen	<b>Directions:</b> 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.
<b>Uses:</b> Helps prevent sunburn.		<b>Other Information:</b> Protect this product from excessive heat and direct sun.
<b>Warnings:</b> 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.		<b>Insect Repellent Active Ingredient:</b> Soybean oil 3% <b>Inactive Ingredients</b> Water, Microcrystalline cellulose, C12-15 Alkyl Benzoate, Isooctyl Palmitate. Propylene Glycol, Glyceryl Stearate Citrate, Disodium EDTA, IodopropynylButylcarbamate, DMDM Hydantoin, Fragrance.
		<b>Drug Questions:</b> 877-254-2281 <b>Distributed By:</b> Tekweld: 45 Rabro Drive, Hauppauge, NY 11788 Made in China

**SPF 30 SUNSCREEN WITH SOYBEAN**

octinoxate, octisalate, oxybenzone, titanium dioxide spray, suspension

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71160-010
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0 596 W) (OCTISALATE - UNII:4X49 Y0 596 W)	OCTISALATE	50 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	20 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
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:71160-010-00	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.