

**TINTED MOISTURIZER SPF 30 SPF 30- octinoxate, titanium dioxide, zinc oxide cream**  
**Regi U.S. 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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**RegiTintedSPF30BrdSpctrmMstrzr3Actvs**

***Active Ingredients***

Octinoxate 7.5%

Titanium Dioxide 3.5%

Zinc Oxide 3%

***Purpose***

Sunscreen

Sunscreen

Sunscreen

***Uses***

• helps prevent Sunburn. • If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

***Warnings***

***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.

## ***Directions***

• apply liberally 15 minutes before sun exposure • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures

including:

- limit time in sun, especially from 10 a.m.- 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

## ***Inactive Ingredients***

Purified Water, Cyclopentasiloxane, Isononyl Isononanoate, Phenyl Trimethicone, Alcohol Denat., Lauryl PEG-8 Dimethicone, Distearidimonium Hectorite, Sodium Chloride, PEG-10 Dimethicone, Talc, Caprylyl Glycol, Alumina, Stearic Acid, Phenoxyethanol, Potassium Sorbate, Sodium Dehydroacetate, Methicone, Hexylene Glycol, Propanediol, Tocopheryl Acetate, Hydrogen Dimethicone, Boerhavia Diffusa Root Extract, Ascorbyl Palmitate MAY CONTAIN: Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891)

## ***Other information***

- protect this product from excessive heat and direct sun

## ***Questions or Comments?***

Call toll free 1-866-983-8582

## ***Package Label***

**Drug Facts**

Active ingredient(s)	Purpose
Octinoxate 7.5%.....	Sunscreen
Titanium Dioxide 3.5%.....	Sunscreen
Zinc Oxide 3%.....	Sunscreen

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**Drug Facts (continued)**

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**Other information**

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**Questions or comments?**  
Call toll free 1-866-953-8582

FREE OF PARABENS, MINERAL OIL, OIL & FRAGRANCE

octinoxate, titanium dioxide, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71692-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3 g in 100 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.5 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SODIUM DEHYDROACETATE</b> (UNII: 8W46YN971G)	
<b>METHICONE (20 CST)</b> (UNII: 6777U11MKT)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HYDROGEN DIMETHICONE (20 CST)</b> (UNII: 12Z59IF64N)	
<b>BOERHAVIA DIFFUSA ROOT</b> (UNII: KR0SR09KYL)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:71692-001-35	35 g in 1 TUBE; Type 0: Not a Combination Product	09/08/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/08/2017	

**Labeler** - Regi U.S. Inc (080161899)

## Establishment

Name	Address	ID/FEI	Business Operations
Regi U.S. Inc		080161899	manufacture(71692-001)

Revised: 1/2023

Regi U.S. Inc