

PROFESSIONAL SOLUTIONS SUNCREEN SPF 30- octinoxate and titanium dioxide lotion
Cosmetic Solutions LLC

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.

Professional Solutions® Sunscreen SPF 30

DRUG FACTS:

ACTIVE INGREDIENTS

Octinoxate 7%

Titanium Dioxide 2.5%

PURPOSE

Sunscreen

USES

Helps prevent sunburn.

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 generously until desired coverage is achieved. If exposed to sun, reapply every 2 hours. If swimming or sweating, use water resistant sunscreen.

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 value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses.

INACTIVE INGREDIENTS

Water (Aqua), Aloe Barbadensis Leaf Extract, Isocetyl Stearate, Sorbitol, Cetearyl Alcohol, Cetareth-20, Tocopheryl Acetate, Acetyl Hexapeptide-8, Hydrolyzed Rice Protein, Alcohol SDA-40, Dimethicone, Octyl Salicylate, Cetyl Alcohol, Sodium Laureth Sulfate, Carbomer, Camellia Sinensis (Green Tea) Leaf Extract, Fragrance, Triethanolamine, Triethoxycaprylylsilane, Lecithin, Caprylyl Glycol, Methylisothiazolinone.

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sun.

Manufactured By:
Professional Solutions
Boca Raton, FL 33487

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Label

Professional
Solutions®
PURE SCIENCE. BETTER SKIN

sunscreen lotion
broad spectrum spf 30
water resistant (40 mins)
protects + moisturizes
2 Fl. Oz. (60mL)



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DRUG FACTS:	
ACTIVE INGREDIENTS:	Purpose
Titanium Dioxide 2.5% , Octinoxate 7%.}	Sunscreen
USES: Help prevent sunburn.	
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 to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure. *Reapply after 40 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours. *For children under 6 months of age: Ask a doctor. 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 value of 15 or higher and other sun protection measures including:	
<ul style="list-style-type: none"> • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses. 	
INACTIVE INGREDIENTS: Water (Aqua), Aloe Barbadensis Leaf Extract, Isocetyl Stearate, Sorbitol, Cetearyl Alcohol, Ceteareth-20, Tocopheryl Acetate, Acetyl Hexapeptide-8, Hydrolyzed Rice Protein, Alcohol SDA-40, Dimethicone, Octyl Salicylate, Cetyl Alcohol, Methicone, Sodium Laureth Sulfate, Carbomer, Camellia Sinensis (Green Tea) Leaf Extract, Fragrance, Triethanolamine, Stearic Acid, Lecithin, Alumina, Caprylyl Glycol, Methylisothiazolinone.	
OTHER INFORMATION: Protect the product in this container from excessive heat and direct sun.	

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Professional Solutions
Boca Raton, FL 33487
www.professionalsolutions.net

  **MADE IN USA**
SP65 LB002749



PROFESSIONAL SOLUTIONS SUNSCREEN SPF 30

octinoxate and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-6500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 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)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Isocetyl Stearate (UNII: 3RJ7186O9W)	
Sorbitol (UNII: 506T60A25R)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Acetyl Hexapeptide-8 (UNII: L4EL31FWIL)	
Dimethicone (UNII: 92RU3N3Y1O)	
Octisalate (UNII: 4X49Y0596W)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Methicone (20 Cst) (UNII: 6777U11MKT)	
Sodium Laureth-3 Sulfate (UNII: BPV390UAP0)	
Carboxypolymethylene (UNII: 0A5MM307FC)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Trolamine (UNII: 9O3K93S3TK)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Aluminum Oxide (UNII: LMI26O6933)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Methylisothiazolinone (UNII: 229D0E1QFA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-6500-2	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/01/2019	

Labeler - Cosmetic Solutions LLC (807907928)