

PROFESSIONAL SOLUTIONS - BOTANICAL DAY CREAM BROAD SPECTRUM SPF 30 SUNSCREEN- octinoxate and zinc oxide cream
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® - Botanical Day Cream Broad Spectrum SPF 30 Sunscreen

DRUG FACTS:

ACTIVE INGREDIENTS

Octinoxate 7.5%, Zinc Oxide 10.0%.

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.

DIRECTIONS

Apply to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure.*Reapply at least every 2 hours. *Use a water-resistant sunscreen if swimming or sweating. *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:

- 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), Butyloctyl Salicylate, Glycerin, Dimethicone, Styrene/Acrylates Copolymer,

Coco-Caprylate/Caprata, Caprylic/Capric Triglyceride, VP/Eicosene Copolymer, Carthamus Tinctorius Oleosomes, Elettaria Cardamomum Seed Extract, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Perilla Frutescens Extract, Pyrus Malus (Apple) Fruit Extract, Rose Extract, Santalum Album Extract, Camellia Sinensis Leaf Extract, Anthemis Nobilis Flower Extract, Cananga Odorata Flower Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Cucumis Melo (Melon) Fruit Extract, Cucumis Sativus Fruit Extract, Jasminum Officinale Flower/Leaf Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Rubus Idaeus (Raspberry) Fruit Extract, Polygonum Aviculare Extract, Vitis Vinifera Fruit Cell Extract, Propanediol, Cetearyl Alcohol, Pentylene Glycol, Arachidyl Alcohol, Polyhydroxystearic Acid, Coco-Glucoside, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Behenyl Alcohol, Xanthan Gum, Triethoxycaprylylsilane, Arachidyl Glucoside, Phenethyl Alcohol, Caprylyl Glycol.

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 g Jar Label

Professional
Solutions®

PURE SCIENCE. BETTER SKIN

daily defense
moisturizer
broad spectrum
spf 30 sunscreen

moisturizes +

net WT. 2 Oz. (60g)

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octinoxate and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-0300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Glycerin (UNII: PDC6A3C0OX)	
Dimethicone (UNII: 92RU3N3Y1O)	
Styrene/Acrylamide Copolymer (500000 MW) (UNII: 5Z4DPO246A)	
Cocoyl Caprylocaprate (UNII: 8D9H4QU99H)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Carthamus Tinctorius Seed Oleosomes (UNII: 9S60Q72309)	
Cardamom (UNII: 8BC4CUT4JL)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Perilla Frutescens Seed (UNII: 8M62PUD356)	
Apple (UNII: B423VGH5S9)	
Santalum Album Seed (UNII: 7RZT0U509Y)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Chamaemelum Nobile Flower (UNII: O2T154T6OG)	
Cananga Odorata Flower (UNII: 76GTF6Z97M)	
Orange Peel (UNII: T19T76XD44)	
Muskmelon (UNII: ZV095H5633)	
Jasminum Officinale Flower (UNII: 0Q8K841432)	
Lavandula Angustifolia Subsp. Angustifolia Flowering Top (UNII: 9YT4B71U8P)	
Raspberry (UNII: 4N14V5R27W)	
Polygonum Aviculare Top (UNII: ZCD6009IUF)	
Propanediol (UNII: 5965N8W85T)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Pentylene Glycol (UNII: 50C1307PZG)	
Arachidyl Alcohol (UNII: 1QR1QRA9BU)	
Coco Glucoside (UNII: ICS790225B)	
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 MPA.S AT 1.5%)	

(UNII: 86FQE96TZ4)	
Docosanol (UNII: 9G1OE216XY)	
Xanthan Gum (UNII: TTV12P4NEE)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Arachidyl Glucoside (UNII: 6JVB35J00J)	
Phenylethyl Alcohol (UNII: ML9LGA7468)	
Caprylyl Glycol (UNII: 00YIU5438U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-0300-0	60 g in 1 JAR; Type 0: Not a Combination Product	01/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/01/2020	

Labeler - Cosmetic Solutions LLC (807907928)

Revised: 1/2023

Cosmetic Solutions LLC