

YOUTH CELL DAY BROAD SPECTRUM SPF-15 SUNSCREEN- avobenzone, octinoxate, octisalate, and octocrylene cream
Illuminage Beauty, 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.

Drug Facts

Active Ingredients

Avobenzone 3%

Octinoxate 6%

Octisalate 3%

Octocrylene 2.4%

Purpose

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 swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- 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

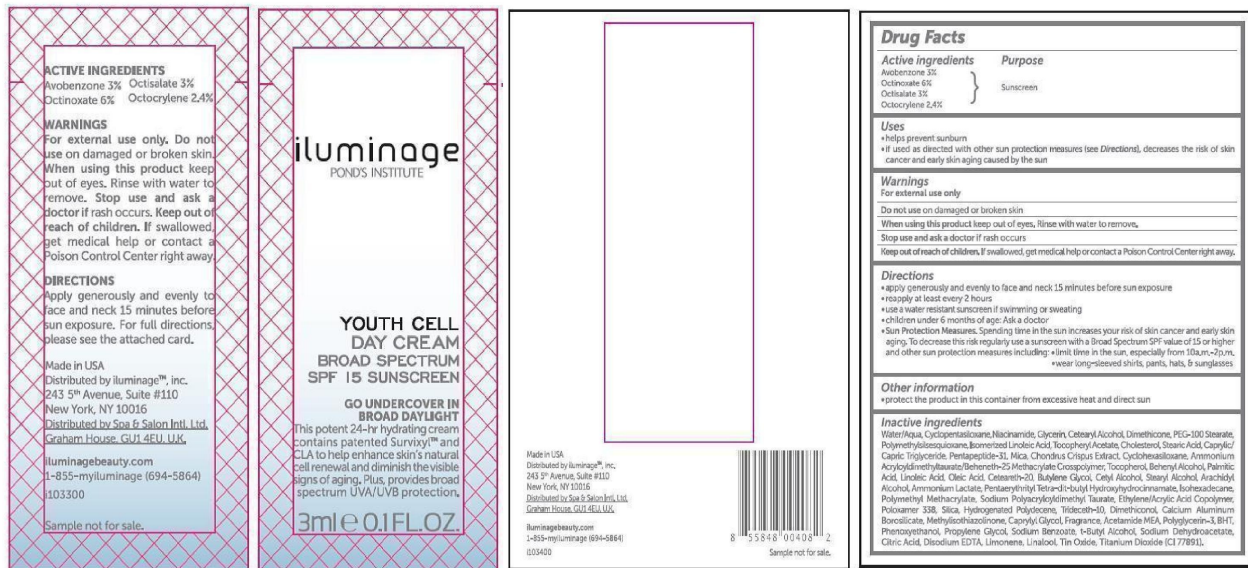
Inactive ingredients

Water/Aqua, Cyclopentasiloxane, Niacinamide, Glycerin, Cetearyl Alcohol, Dimethicone, PEG-100 Stearate, Poly-Methylsilsesquixane, Isomerized Linoleic Acid, Tocopheryl Acetate, Cholesterol, Stearic Acid, Caprylic/Capric Triglyceride, Pentapeptide-31, Ammonium Acryloyldimethyltaurate/Beheneth-25 Methylacrylate Crosspolymer, Tocopherol, Behenyl Alcohol, Palmitic Acid, Linoleic Acid, Oleic Acid, Cetareth-20, Butylene Glycol, Cetyl Alcohol, Stearyl Alcohol, Arachidyl Alcohol, Ammonium Lactate, Pentaerythryl Tetra-di-t-butyl Hydroxyhydrocinnamate, Isohexadecane, Poly-Methyl Methacrylate, Sodium Polyacryloyldimethyl Taurate, Ethylene/Acrylic Acid Copolymer, Poloxamer 338, Silica, Hydrogenated Polydecene, Trideceth-10, Dimethiconol, Calcium Aluminum Borosilicate, Methylisothiazolinone, Caprylyl Glycol, Fragrance, Acetamide MEA, Polyglycerin-3, BHT, Phenoxyethanol, Propylene Glycol, Sodium Benzoate, Citric Acid, Disodium EDTA, Limonene, Linalool, tin Oxide. Titanium Dioxide (CI 77891).

Other information

protect the product in this container from excessive heat and direct sun

Label



YOUTH CELL DAY BROAD SPECTRUM SPF-15 SUNSCREEN

avobenzone, octinoxate, octisalate, and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69047-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 mg in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3 mg in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	2.4 mg in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ACETAMIDE (UNII: 8XOE1JSO29)	

AMMONIUM ACRYLOYLDIMETHYLTAURATE/BEHENETH-25 METHACRYLATE CROSSPOLYMER (52000 MPA.S) (UNII: LZ291VH90H)	
AMMONIUM LACTATE (UNII: 67M901L9NQ)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
ISOHEXADECANE (UNII: 918X10UF1E)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
MICA (UNII: V8A1AW0880)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OLEIC ACID (UNII: 2UM9U37CP)	
PALMITIC ACID (UNII: 2V16EO95HI)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLOXAMER 338 (UNII: F75JV2T505)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECETH-10 (UNII: G624N6MSBA)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69047-001-04	1 in 1 CARTON	10/16/2013	
1	NDC:69047-001-03	3 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/16/2013	

Labeler - Illuminage Beauty, Inc. (032551374)

Revised: 1/2015

Illuminage Beauty, Inc.