LIGHT DAY SUNSCREEN BROAD SPECTRUM SPF 37- avobenzone, octinoxate and octocrylene lotion Circadia by Dr Pugliese, 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.

Light Day Sunscreen

Active ingredient

Avobenzone 3.0%

Octinoxate 7.5%

Octocrylene 2.8%

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
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs.
- **Do not use** on damaged or broken skin
- **Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally to skin 15 minutes before sun exposure and as needed.
- use a water resistant sunscreen if swimming or sweating.
- reapply at least every 2 hours.
- children under 6 months: 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 15 or higher and other sun protection measures including:
 - o limit time in the sun, especially from 10 a.m. 2 p.m.
 - wear long-sleeved shirt, pants, hats, and sunglasses

Inactive ingredients

Water, C12-15 Alkyl Benzoate, Ethylhexyl Methoxycrylene, Glycerin, Silica, Eicosene Copolymer, Glyceryl Stearate, PEG-100 Stearate, Potassium Cetyl Phosphate, Dimethicone, Cyclopentasiloxane, Cyclohexasiloxane, Dimethyl Capramide, Hydrogenated Palm Glycerides, Polysiloxane 11, Dimethylmethoxy Chromanol, Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer,

Diaminopropionoyl Tripeptide-33, Caprylyl Glycol, Disodium EDTA, Xanthan Gum, Methylisothiazolinone, Hexylene Glycol, Isohexadecane, Polysorbate 80, Vitis Vinifera Fruit Cell Extract, Isomalt, Prunus Armeniaca (Apricot) Fruit Extract, Lecithin, Sodium Benzoate, Aniba Rosaeodora (Rosewood) Wood Extract, Citrus Aurantifolia (Lime) Peel Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Vanilla Planifolia Fruit Extract, Citrus Grandis (Grapefruit) Peel Extract, Cocos Nucifera (Coconut) Oil

Other Information

• protect this product from excessive heat and direct sun.

Questions?

Call toll-free (800) 630-4710

Package/Label Principal Display Panel

Light Day Sunscreen for face & neck Broad Spectrum SPF37 Advanced Professional Skincare 2 fl oz (59 ml)

Circadia by Dr. Pugliese, Inc. 8371 Route 183 Bethel, PA 19507 Circadia.com

High sun protection product

Drug Facts

Active Ingredients

Purpose

Avobenzone 3.0% Octinoxate 7.5% Octocrylene 2.8%

Sunscreen

Uses

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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.

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 Measures: Spending
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 aging. To decrease this
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 sunscreen with a Broad
 Spectrum SPF 15 or
 higher and other sun
 protection measures
 including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
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Dermatologist Tested



Drug Facts (Continued)

Inactive ingredients

Water, C12-15 Alkyl Benzoate, Ethylhexyl Methoxycrylene, Glycerin, Silica, VP/Eicosene Copolymer, Glyceryl Stearate, PEG-100 Stearate, Potassium Cetyl Phosphate, Dimethicone, Cyclopentasiloxane, Cyclohexasiloxane, Dimethyl Capramide, Hydrogenated Palm Glycerides, Polysiloxane-11, Dimethylmethoxy Chromanol, Acrylamide/ Sodium Acryloyldimethyltaurate Copolymer, Diaminopropionoyl Tripeptide-33, Caprylyl Glycol, Disodium EDTA, Xanthan Gum, Methyl sothiazolinone, Hexylene Glycol, Isohexadecane, Polysorbate 80, Prunus Armeniaca (Apricot) Fruit Extract, Aniba Rosaeodora (Rosewood) Wood Extract, Citrus Aurantifolia (Lime) Peel Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Vanilla Planifora Fruit Extract, Citrus Grandis (Grapefruit) Peel Extract, Cocos Nucifera (Coconut) Oil, Vitis Vinifera Fruit Cell Extract, Isomalt, Lecithin, Sodium Benzoate.

Other information

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Light Day Sunscreen for face & neck

Broad Spectrum SPF 37

Advanced Professional Skincare

2 fl oz (59 ml)

Circadia by Dr. Pugliese, Inc. 8371 Route 183 Bethel, PA 19507 Circadia.com

LIGHT DAY SUNSCREEN BROAD SPECTRUM SPF 37

avobenzone, octinoxate and octocrylene lotion

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:76458-201

Route of Administration TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 mL in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 mL in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	0.028 mL in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POTASSIUM CETYL PHO SPHATE (UNII: 03KCY6P7UT)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
DIMETHYL CAPRAMIDE (UNII: O29 Y6 X2JEZ)	
HYDRO GENATED PALM GLYCERIDES (UNII: YCZ8 EM144Q)	
SODIUM ACRYLATE/SODIUM ACRYLO YLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
ISOHEXADECANE (UNII: 918 X10 UF1E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ISOMALT (UNII: S870P55O2W)	
APRICOT (UNII: 269CJD5GZ9)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANIBA ROSAEODORA WOOD (UNII: NE0 1NKA8 B2)	
LIME PEEL (UNII: 544EQK5Q0W)	
ORANGE PEEL (UNII: TI9T76 XD44)	
VANILLA (UNII: Q74T35078H)	
CITRUS MAXIMA FRUIT RIND (UNII: 5NX3G75CA6)	
COCONUT OIL (UNII: Q9L0O73W7L)	

WINE GRAPE (UNII: 3GOV20705G)								
Packaging								
# Item Code	Package Description	Marketing Start Date		Marketing End Date				
1 NDC:76458-201-02	59 mL in 1 BOTTLE, PUMP							
Marketing Information								
Marketing Category	Application Number or Monograph Citation		Marketing Start Da	te Marketing End Date				
OTC monograph not final	part352		07/15/2012					

Labeler - Circadia by Dr Pugliese, Inc. (013694423)

Revised: 8/2012 Circadia by Dr Pugliese, Inc.