

**SOL LEON SUNSCREEN SPF 15 - avobenzone, homosalate, octisalate, octocrylene cream
Bottega di Lungavita Srl**

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.

SOL LEON Sunscreen SPF 15

Drug Facts

Active Ingredients

Avobenzone	3%
Homosalate	8%
Octisalate	5%
Octocrylene	8%

Purpose

Sunscreen

Uses

- Provides moderate protection against sunburn.
- For skin that sunburns easily.

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 or irritation develops and lasts

Directions

- Apply evenly before sun exposure.
- Children under 6 months of age, ask a doctor.
- Reapply as needed or after towel drying, swimming or perspiring.

Inactive Ingredients

Water, caprylic/capric triglyceride, c12-15 alkyl benzoate, octocrylene, homosalate, butyl methoxydibenzoylmethane, tricontanyl pvp, cyclopentasioxane, glyceryl stearate, propylene glycol, glycerin, steareth-21, dimethicone, stearic acid, aloe barbadensis gel, maltodextrin, steareth-2, phenoxyethanol, ethylhexylsalicylate, bis-peg-18 methyl ether dimethyl silane, parfum (fragrance), glycine soja oil (soybean oil), peg-100 stearate, tocopheryl acetate, potassium sorbate, carbomer, oryza sativa cera (rice wax), methylparaben, ethylparaben, propylparaben, bisabolol, retinyl palmitate, alumina, panthenol, tetrasodium edta, silica, sodium polyacrylate, daucus carota extract (carrot root extract), lecithin, butylparaben, tocopherol. ascorbyl palmitate, sodium hydroxide, juglans regia leaf extract (walnut extract), betacarotene, citric acid.

Manufactured For:

Bottega Di Lungavita Srl

Via Verga, 14

Bergamo, Italia I-24127

Italy

Made in Italy

Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Ultra protection cream for the body and delicate areas of the face. It is particularly suitable for sensitive skin and ensures the perfect protection of children's delicate skin. Moisturizes and prevents sunburn, age-spots and skin rashes.

SOL

LEON

Sunscreen

SPF 15

UVA UVB

MEDIUM PROTECTION

Contains Carrot Extract

Bottega Di

Lungavita

Natural Products

Italian Style of Life

8.45 fl oz (250 mL)

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silica, sodium polyacrylate, daucus carota extract (carrot root extract), lecithin, butylparaben, tocopherol, ascorbyl palmitate, sodium hydroxide, juglans regia leaf extract (walnut extract), betacarotene, citric acid.

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SOL[®]
LEON



Sunscreen SPF 15

UVA UVB

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Contains
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Italian Style of life

8.45 fl oz (250 mL)

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avobenzone, homosalate, octisalate, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75944-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
OCTOCRYLENE (UNII: 5A68WGF6WM)	
HOMOSALATE (UNII: V06SV4M95S)	
AVOBENZONE (UNII: G63QQF2NOX)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARETH-21 (UNII: 53J3F32P58)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARETH-2 (UNII: V56DFE46J5)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
OCTISALATE (UNII: 4X49Y0596W)	
SOYBEAN (UNII: L7HT8F1ZOD)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYL PARABEN (UNII: 14255EXE39)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
LEVOMENOL (UNII: 24WE03BX2T)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALUMINUM OXIDE (UNII: LM26O6933)	
PANTHENOL (UNII: WV9CM0O67Z)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARROT (UNII: L56Z1JK48B)	
BUTYL PARABEN (UNII: 3QPIU3FV8)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
JUGLANS REGIA LEAF (UNII: 85HKB87105)	
BETA CAROTENE (UNII: 01YAE03M7J)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75944-100-00	250 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/15/2010	

Labeler - Bottega di Lungavita Srl (431933910)

Establishment

Name	Address	ID/FEI	Business Operations
O.F.I. Spa / OFI Officina Farmaceutica Italiana SpA		434907226	manufacture

Revised: 1/2011

Bottega di Lungavita Srl