

**SOL LEON SUNSCREEN SPF 30 - avobenzene, homosalate, octisalate, octocrylene, octinoxate 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.*

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**SOL LEON Sunscreen SPF 30**

Drug Facts

Active Ingredients

Avobenzene	3%
Homosalate	8%
Octisalate	5%
Octocrylene	8%
Octinoxate	7.5%

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, c12-15 alkyl benzoate, homosalate octocrylene, ethylhexylmethoxycinnamate, Glycerin, cocglycerides, dimethicone, tridecyl salicylate, Ethylhexyl salicylate, butyl methoxydibenzoylmethane, tricontanyl pvp, glyceryl stearate, steareth-21, stearic acid, caprylic/capric triglyceride, aloe barbadensis gel, Maltodextrin, steareth-2, phenoxyethanol, parfum, Fragrance, peg-100 stearate, tocopheryl acetate, Xanthan gum, daucus carota extract (carrot extract), Potassium sorbate, alumina, oryza sativa cera ( rice wax), methylparaben, acrylates c10-30 alkyl acrylate Crosspolymer, dichlorobenzyl alcohol, ethylparaben, propylparaben, bisabolol, retinyl palmitate, propylene glycol, silica, panthenol, sodium polyacrylate, Hydrolyzed rice protein, hydrolyzed vegetable protein, tetrasodium edta, glicerina, sodium hydroxide, butylparaben, juglans regia leaf extract (walnut extract), BHT.

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 sun cream particularly suitable for children and those with fair and delicate skins. It ensures protection against sunburn and prevents skin rashes and age-spots.

SOL

LEON

Sunscreen

SPF 30

UVA UVB

HIGH PROTECTION

Contains Carrot Extract

Bottega Di

Lungavita

Natural Products

Italian Style of Life

6.76 fl oz (200 mL)

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butyl methoxydibenzoylmethane, Tricontanyl pvp, glyceryl stearate, steareth-21, stearic Acid, caprylic/capric triglyceride, aloe barbadensis gel, Maltodextrin, steareth-2, phenoxyethanol, parfum, Fragrance, peg-100 stearate, tocopheryl acetate, Xanthan gum, daucus carota extract (carrot extract), Potassium sorbate, alumina, oryza sativa cera (rice Wax), methylparaben, acrylates/c10-30 alkyl acrylate Crosspolymer, dichlorobenzyl alcohol, ethylparaben, Propylparaben, bisabolol, retinyl palmitate, propylene Glycol, silica, panthenol, sodium polyacrylate, Hydrolyzed rice protein, hydrolyzed vegetable protein, Tetrasodium edta, glicerina, sodium hydroxide, Butylparaben, juglans regia leaf extract (walnut Extract), BHT.

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**SOL<sup>®</sup>**  
**LEON**

LEON

# Sunscreen SPF 30



HIGH PROTECTION

Contains  
Carrot Extract



*Italian Style of life*

**6.76 fl oz (200 mL)**

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avobenzone, homosalate, octisalate, octocrylene, octinoxate cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75944-200
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 mL in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mL in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 mL in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>C12-15 ALKYL BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>HOMOSALATE</b> (UNII: V06SV4M95S)	
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM)	
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>COCO-GLYCERIDES</b> (UNII: ISE9I7DNUG)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>OCTISALATE</b> (UNII: 4X49Y0596W)	
<b>AVOBENZONE</b> (UNII: G63QQF2NOX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>STEARETH-2</b> (UNII: V56DFE46J5)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYOXYL 100 STEARATE</b> (UNII: YD01N1999R)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CARROT</b> (UNII: L56Z1JK48B)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>DICHLOROBENZYL ALCOHOL</b> (UNII: 1NKX3648J9)	
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	

<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>BUTYL PARABEN</b> (UNII: 3QP1U3FV8)	
<b>JUGLANS REGIA LEAF</b> (UNII: 85HKB87105)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75944-200-00	200 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