

**CLINIQUE SPF 15 WITH SOLAR SMART ADVANCED PROTECTION- homosalate, octisalate, avobenzone, and octocrylene cream  
CLINIQUE LABORATORIES 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.*

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**CLINIQUE  
SPF  
15  
with  
SolarSmart**

**TO USE**

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

**WARNING**

For external use only. Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help right away.

**ACTIVE INGREDIENTS**

HOMOSALATE 10.0% • OCTISALATE 5.0% • AVOBENZONE 3.0% • OCTOCRYLENE 2.7%

**INGREDIENTS**

WATER • BUTYLENE GLYCOL • ISONONYL ISONONANDATE • BUTYLOCTYL SALICYLATE • TRIACONTANYL PVP • POLYESTER-8 • SILICA • ROSMARINUS OFFICINALIS (ROSEMARY) EXTRACT • PERILLA OCYMOIDES LEAF EXTRACT • STEARYL DIMETHICONE • CAFFEINE • PLANKTON EXTRACT • SUCROSE • HYDROGENATED LECITHIN • POTASSIUM CETYL PHOSPHATE • LAURDIMONIUM HYDROXYPROPYL HYDROLYZED SOY PROTEIN • PEG-100 STEARATE • CETYL ALCOHOL • POLYETHYLENE • ACRYLIC ACID/VP CROSSPOLYMER • VP/EICOSENE COPOLYMER • TOCOPHERYL ACETATE • TROMETHAMINE • SODIUM RNA • ALOE BARBADENSIS POWDER • PHOSPHOLIPIDS • LECITHIN • MAGNESIUM ASCORBYL PHOSPHATE • SODIUM HYALURONATE • HYDROXYPROPYL METHYLCELLULOSE • C1-8 ALKYL TETRAHYDROXYCYCLOHEXANOATE • HYDROXYETHYLCELLULOSE • ASCORBYL TOCOPHERYL MALEATE • MALTODEXTRIN • CAPRYLYL GLYCOL • HEXYLENE GLYCOL • NORDIHYDROGUAIARETIC ACID • FERULIC ACID • DISODIUM EDTA • PHENOXYETHANOL • CHLORPHENESIN • MICA [ILN34995]

CLINIQUE LABORATORIES, DIST. NEW YORK, N.Y. 10022

**PRINCIPAL DISPLAY PANEL - 150 ml Carton**

**CLINIQUE  
SPF  
15**

**with SolarSmart**

**UVA UVB  
advanced  
protection**

face/body  
cream

5 FL. OZ.

150 ml e

# CLINIQUE

SPF  
**15**

with  
SolarSmart



face/body  
cream

5 FL.OZ.  
150 ml e

**Allergy Tested. 100% Fragrance Free.**  
**Dermatologist Tested.**

**Worship your skin™.** Our new dimension in protection — advanced defense and repair. Innovative SolarSmart technology stabilizes high-level protection against the aging and burning effects of UVA and UVB rays. Triggers a repair that helps prevent signs of aging. Formulated for face with solar-activated antioxidants that help prevent visible damage. See enclosure.

- Oil-free
- Water-resistant
- PABA-free
- Non-acnegenic
- Sweat-resistant
- Appropriate for sensitive skins

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**ACTIVE INGREDIENTS:** HOMOSALATE 10.0% • OCTISALATE 5.0% • AVOBENZONE 3.0% • OCTOCRYLENE 2.7%

**INGREDIENTS:** WATER/AQUA/EAU • BUTYLENE GLYCOL • ISONONYL ISONONANATE • BUTYLOCTYL SALICYLATE • TRIACONTANYL PVP • POLYESTER-8 • SILICA • ROSMARINUS OFFICINALIS (ROSEMARY) EXTRACT • PERILLA OCYMOIDES LEAF EXTRACT • STEARYL DIMETHICONE • CAFFEINE • PLANKTON EXTRACT • SUCROSE • HYDROGENATED LECITHIN • POTASSIUM CETYL PHOSPHATE • LAURDIMONIUM HYDROXYPROPYL HYDROLYZED SOY PROTEIN • PEG-100 STEARATE • CETYL ALCOHOL • POLYETHYLENE-ACRYLIC ACID/VP CROSSPOLYMER • VP/EICOSENE COPOLYMER • TOCOPHERYL ACETATE • TROMETHAMINE • SODIUM RNA • ALOE BARBADENSIS POWDER • PHOSPHOLIPIDS • LECITHIN • MAGNESIUM ASCORBYL PHOSPHATE • SODIUM HYALURONATE • HYDROXYPROPYL METHYLCELLULOSE • C1-8 ALKYL TETRAHYDROXYCYCLOHEXANOATE • HYDROXYETHYLCELLULOSE • ASCORBYL TOCOPHERYL MALEATE • MALTODEXTRIN • CAPRYLYL GLYCOL • HEXYLENE GLYCOL • NORDIHYDROGUAIARETIC ACID • FERULIC ACID • DISODIUM EDTA • PHENOXYETHANOL • CHLORPHENESIN • MICA [ILN34995]



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NEW YORK • LONDON W1K 3BQ • PARIS  
MADE IN U.S.A. 6NH8



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## CLINIQUE SPF 15 WITH SOLAR SMART ADVANCED PROTECTION

homosalate, octisalate, avobenzone, and octocrylene cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49527-735
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>homosalate</b> (UNII: V06SV4M95S) (homosalate - UNII:V06SV4M95S)	homosalate	10 mL in 100 mL
<b>octisalate</b> (UNII: 4X49 Y0596W) (octisalate - UNII:4X49 Y0596W)	octisalate	5 mL in 100 mL
<b>avobenzene</b> (UNII: G63QQF2NOX) (avobenzene - UNII:G63QQF2NOX)	avobenzene	3 mL in 100 mL
<b>octocrylene</b> (UNII: 5A68WGF6WM) (octocrylene - UNII:5A68WGF6WM)	octocrylene	2.7 mL in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>water</b> (UNII: 059QF0KO0R)	
<b>butylene glycol</b> (UNII: 3XUS85K0RA)	
<b>isononyl isononanoate</b> (UNII: S4V5BS6GCX)	
<b>butyloctyl salicylate</b> (UNII: 2EH13UN8D3)	
<b>triacontanyl pvp (wp-660)</b> (UNII: N0SS3Q238D)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>rosemary</b> (UNII: IJ67X351P9)	
<b>perilla frutescens leaf</b> (UNII: T4L5881Y68)	
<b>caffeine</b> (UNII: 3G6A5W338E)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)	
<b>peg-100 stearate</b> (UNII: YD01N1999R)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>high density polyethylene</b> (UNII: UG00KM4WR7)	
<b>.alpha.-tocopherol acetate</b> (UNII: 9E8X80D2L0)	
<b>tromethamine</b> (UNII: 023C2WHX2V)	
<b>magnesium ascorbyl phosphate</b> (UNII: 0R822556M5)	
<b>hyaluronate sodium</b> (UNII: YSE9PPT4TH)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
<b>hexylene glycol</b> (UNII: KEH0A3F75J)	
<b>masoprocol</b> (UNII: 7BO8G1BYQU)	
<b>ferulic acid</b> (UNII: AVM951ZWST)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>chlorphenesin</b> (UNII: I670DAL4SZ)	
<b>mica</b> (UNII: V8A1AW0880)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:49527-735-01	1 in 1 CARTON		
1		150 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/01/2009	

**Labeler** - CLINIQUE LABORATORIES INC. (173047747)

## Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(49527-735) , REPACK(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(49527-735) , RELABEL(49527-735) , REPACK(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Inc.		042918826	MANUFACTURE(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(49527-735) , RELABEL(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(49527-735) , RELABEL(49527-735) , REPACK(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(49527-735) , RELABEL(49527-735) , REPACK(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(49527-735) , RELABEL(49527-735) , REPACK(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(49527-735)

## Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(49527-735) , RELABEL(49527-735)

Revised: 8/2012

CLINIQUE LABORATORIES INC.