

**CLINIQUE SPF 30 WITH SOLAR SMART- octisalate, homosalate, oxybenzone, 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  
30  
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**

OCTISALATE 5.0% • HOMOSALATE 5.0% • OXYBENZONE 4.0% • AVOBENZONE 3.0% • OCTOCRYLENE 2.7%.

**INGREDIENTS**

WATER • METHYL TRIMETHICONE • BUTYLENE GLYCOL • BUTYLOCTYL SALICYLATE • NEOPENTYL GLYCOL DIHEPTANOATE • BUTYROSPERMUM PARKII (SHEA BUTTER) • PEG-100 STEARATE • SILICA • DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE • LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • DIMETHICONE • GLYCERYL STEARATE • LAURDIMONIUM HYDROXYPROPYL HYDROLYZED SOY PROTEIN • ROSMARINUS OFFICINALIS (ROSEMARY) EXTRACT • PERILLA OCYMOIDES LEAF EXTRACT • PLANKTON EXTRACT • CAFFEINE • POTASSIUM CETYL PHOSPHATE • SUCROSE • STYRENE/ACRYLATES COPOLYMER • C30-38 OLEFIN/ISOPROPYL MALEATE/MA COPOLYMER • CETYL ALCOHOL • VP/EICOSENE COPOLYMER • ETHYLHEXYLGLYCERIN • AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER • PEG-8 LAURATE • SODIUM RNA • PHOSPHOLIPIDS • LECITHIN • C1-8 ALKYL TETRAHYDROXYCYCLOHEXANOATE • HYDROXYETHYLCELLULOSE • TOCOPHERYL ACETATE • CAPRYLYL GLYCOL • ASCORBYL TOCOPHERYL MALEATE • STEARIC ACID • XANTHAN GUM • MALTODEXTRIN • FERULIC ACID • HEXYLENE GLYCOL • NORDIHYDROGUAIARETIC ACID • DISODIUM EDTA • PHENOXYETHANOL • MICA • SODIUM DEHYDROACETATE [ILN35074]

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

**PRINCIPAL DISPLAY PANEL - 50 ml Carton**

**CLINIQUE**

**SPF**

**30**

**with**

**SolarSmart**

**UVA UVB**

**advanced**

**protection**

face cream

1.7 FL. OZ.

50 ml e

UNIQUE

SPF  
30  
with  
SolarSmart

UVA UVB  
advanced  
protection



face cream

1.7 FL.OZ.  
50 ml e

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

DIHEPTANOATE • BUTYROSPERMUM PARKII (SHEA BUTTER) • PEG-100 STEARATE • SILICA • DIPENTAERYTHRITYL TRI-POLY-HYDROXYSTEARATE • LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • DIMETHICONE • GLYCERYL STEARATE • LAURDIMONIUM HYDROXYPROPYL HYDROLYZED SOY PROTEIN • ROSMARI- NUS OFFICINALIS (ROSEMARY) EXTRACT • PERILLA OCYMOIDES LEAF EXTRACT • PLANKTON EX- TRACT • CAFFEINE • POTASSIUM CETYL PHOSPHATE • SUCROSE • STYRENE/ACRYLATES COPOLY- MER • C30-38 OLEFIN/ISOPROPYL MALEATE/MA COPOLYMER • CETYL ALCOHOL • VP/EICOSENE COPOLY- MER • ETHYLHEXYLGLYCERIN • AM- MONIUM ACRYLDYLDIMETHYL- TAURATE/VP COPOLYMER • PEG-8 LAURATE • PEG-100 STEARATE

- Sweat-resistant

- Appropriate for sensitive skins

**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:** OCTISALATE 5.0% • HOMOSALATE 5.0% • OXYBENZONE 4.0% • AVOBENZONE 3.0% • OCTOCRYLENE 2.7%.  
**INGREDIENTS:** WATER/AQUA/EAU • METHYL TRIMETHICONE • BUTYLENE GLYCOL • BUTYL-OCTYL SALICYLATE • NEOPENTYL GLYCOL ▶

LAURATE • SODIUM RNA • PHOSPHOLIPIDS • LECITHIN • C-1-8 ALKYL TETRAHYDROXYCYCLOHEXANOATE • HYDROXYETHYLCELLULOSE • TOCOPHERYL ACETATE • CAPRYLYL GLYCOL • ASCORBYL TOCOPHERYL MALEATE • STEARIC ACID • XANTHAN GUM • MALTODEXTRIN • FERULIC ACID • HEXYLENE GLYCOL • NORDIHYDROGUAIARETIC ACID • DISODIUM EDTA • PHENOXYETHANOL • MICA • SODIUM DEHYDROACETATE [ILN35074]



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NEW YORK, N.Y. 10022  
LONDON W1K 3BQ • PARIS  
MADE IN U.S.A.  
6NH4



clinique.com

## CLINIQUE SPF 30 WITH SOLAR SMART

octisalate, homosalate, oxybenzone, avobenzone, and octocrylene cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49527-716
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
octisalate (UNII: 4X49Y0596W) (octisalate - UNII:4X49Y0596W)	octisalate	5 mL in 100 mL
homosalate (UNII: V06SV4M95S) (homosalate - UNII:V06SV4M95S)	homosalate	5 mL in 100 mL
oxybenzone (UNII: 95OOS7VE0Y) (oxybenzone - UNII:95OOS7VE0Y)	oxybenzone	4 mL in 100 mL
avobenzone (UNII: G63QQF2NOX) (avobenzone - UNII:G63QQF2NOX)	avobenzone	3 mL in 100 mL
octocrylene (UNII: 5A68WGF6WM) (octocrylene - UNII:5A68WGF6WM)	octocrylene	2.7 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
methyl trimethicone (UNII: S73ZQ10GXM)	
butylene glycol (UNII: 3XUS85K0RA)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
neopentyl glycol diheptanoate (UNII: 5LKW3C543X)	
shea butter (UNII: K49155WL9Y)	
peg-100 stearate (UNII: YD01N1999R)	
silicon dioxide (UNII: ETJ7Z6XBU4)	

<b>dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>rosemary</b> (UNII: IJ67X351P9)	
<b>perilla frutescens leaf</b> (UNII: T4L5881Y68)	
<b>caffeine</b> (UNII: 3G6A5W338E)	
<b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	
<b>ethylhexylglycerin</b> (UNII: 147D247K3P)	
<b>peg-8 laurate</b> (UNII: 762O8IWA10)	
<b>alpha-tocopherol acetate</b> (UNII: 9E8X80D2L0)	
<b>caprylyl glycol</b> (UNII: 00YIU5438U)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>xanthan gum</b> (UNII: TTV12P4NEE)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>ferulic acid</b> (UNII: AVM951ZWST)	
<b>hexylene glycol</b> (UNII: KEH0A3F75J)	
<b>masoprocol</b> (UNII: 7BO8G1BYQU)	
<b>edetate disodium</b> (UNII: 7FLD91C86K)	
<b>phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>mica</b> (UNII: V8A1AW0880)	
<b>sodium dehydroacetate</b> (UNII: 8W46YN971G)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-716-01	1 in 1 CARTON		
1		50 mL in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	09/01/2010	

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

### Establishment

Name	Address	ID/FEI	Business Operations
ELGC Kabushiki Kaisha		712808195	RELABEL, REPACK

### Establishment

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

### Establishment

Name	Address	ID/FEI	Business Operations
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ARAMIS, INC		042918826	MANUFACTURE
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<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK, RELABEL

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		787336577	MANUFACTURE, RELABEL, REPACK

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		949264774	MANUFACTURE, RELABEL, REPACK

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		618107429	MANUFACTURE, RELABEL, REPACK

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE

