

**CLINIQUE BROAD SPECTRUM SPF 30 SUNSCREEN FACE WITH SOLAR SMART-  
avobenzone, homosalate, octisalate, octocrylene, and oxybenzone cream  
CLINIQUE LABORATORIES LLC**

*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 BROAD SPECTRUM SPF 30 SUNSCREEN FACE CREAM WITH SOLAR  
SMART**

***Drug Facts***

**Active ingredients**

Avobenzone 3.0%  
Homosalate 5.0%  
Octisalate 5.0%  
Octocrylene 2.7%  
Oxybenzone 4.0%

**Purpose**

Sunscreen

**Use**

helps prevent sunburn

**Warnings**

**For external use only**

**Do not use** on damaged or broken skin

**When using this product** keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor if** rash occurs

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating
- **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 value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. – 2 p.m.
  - wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

## Inactive ingredients

water/aqua/eau • methyl trimethicone • butylene glycol • butyloctyl salicylate • neopentyl glycol diheptanoate • butyrospermum parkii (shea butter) • peg-100 stearate • silica • dipentaerythryl 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 acryloyldimethyltaurate/vp copolymer • peg-8 laurate • sodium rna • lecithin • propyl gallate • arginine ferulate • tocopheryl acetate • caprylyl glycol • ascorbyl tocopheryl maleate • stearic acid • xanthan gum • hexylene glycol • nordihydroguaiaretic acid • disodium edta • phenoxyethanol • mica • sodium dehydroacetate [iln37116]

## Other information

protect the product in this container from excessive heat and direct sun

## PRINCIPAL DISPLAY PANEL - 50 ml Tube Carton

CLINIQUE

broad  
spectrum  
SPF 30  
sunscreen

with  
SolarSmart

UVA UVB  
PROTECTION

face cream

1.7 FL. OZ.  
50 ml e

broad  
spectrum  
SPF 30  
sunscreen  
with  
SolarSmart

UVA UVB  
PROTECTION

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CLINIC

broad  
spectrum  
SPF 30  
sunscreen

with  
SolarSmart

UVA UVB  
PROTECTION

face cream

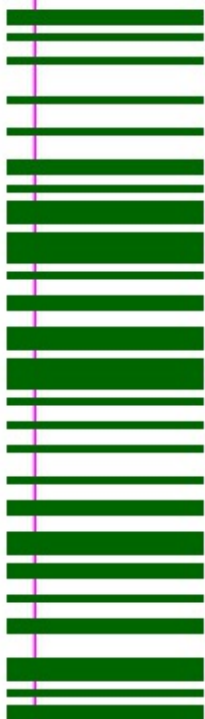
1.7 FL.OZ.  
50 ml e

**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
- PABA-free
- Non-acnegenic
- Appropriate for sensitive skins





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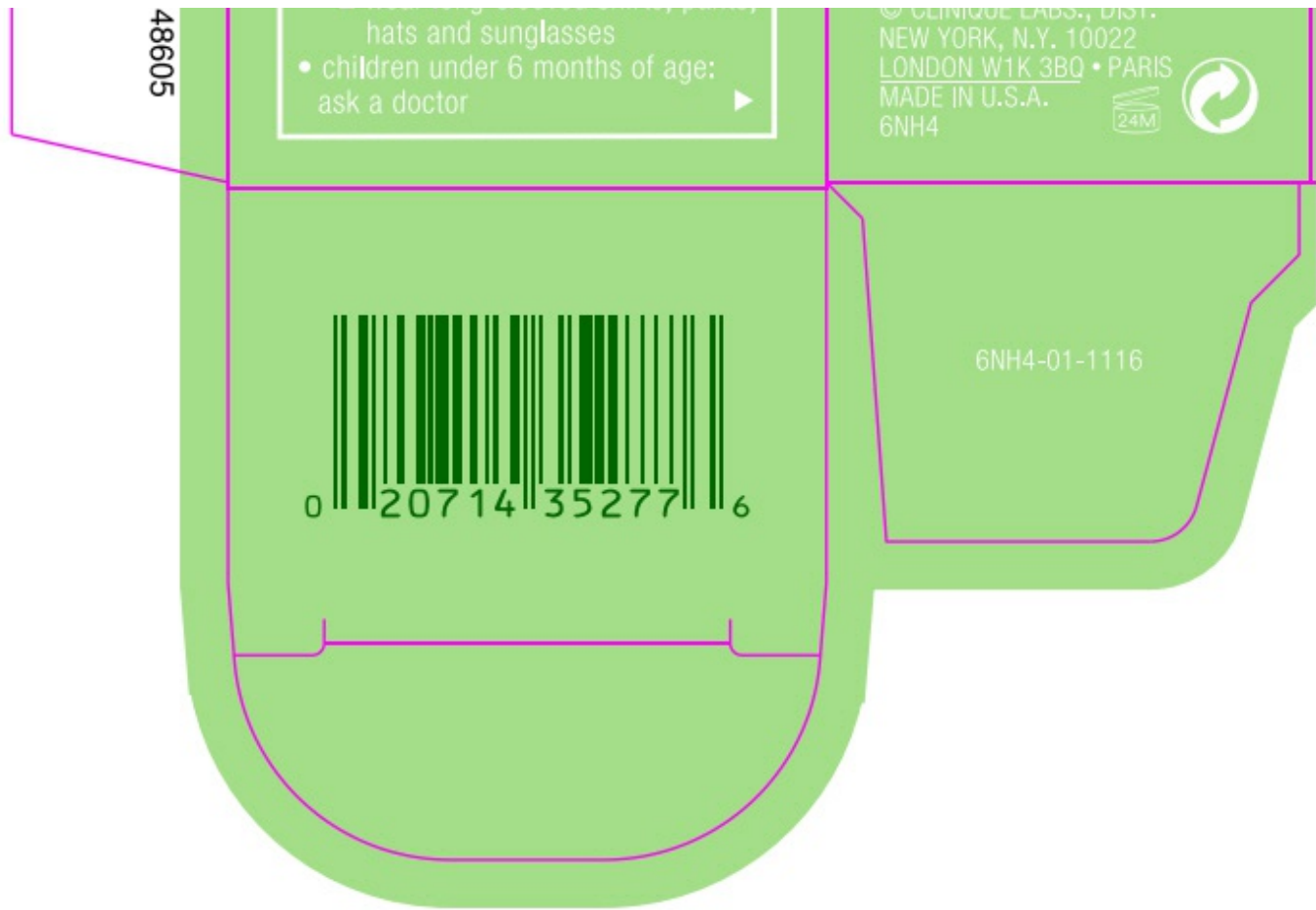
### Drug Facts (cont'd)

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avobenzone, homosalate, octisalate, octocrylene, and oxybenzone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-064
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.0309 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.0515 g in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.0515 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.0278 g in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	0.0412 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
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)
DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE (UNII: D21K655H52)
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)
DIMETHICONE (UNII: 92RU3N3Y1O)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
ROSEMARY (UNII: IJ67X351P9)
CAFFEINE (UNII: 3G6A5W338E)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
SUCROSE (UNII: C151H8M554)
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)
CETYL ALCOHOL (UNII: 936JST6JCN)
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)
PEG-8 LAURATE (UNII: 762O8IWA10)
PROPYL GALLATE (UNII: 8D4SNN7V92)
ARGININE FERULATE (UNII: 0774Y45BEE)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
ASCORBYL TOCOPHERYL MALEATE (UNII: D2G6259XR5)
STEARIC ACID (UNII: 4ELV7Z65AP)
XANTHAN GUM (UNII: TTV12P4NEE)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
MICA (UNII: V8A1AW0880)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-064-01	1 in 1 CARTON	09/01/2010	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

### 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 LLC (044475127)

### Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-064) , REPACK(49527-064)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-064)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-064)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-064)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-064)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
NORTHTEC INC		943871157	RELABEL(49527-064) , REPACK(49527-064)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
PADC 1		949264774	RELABEL(49527-064) , REPACK(49527-064)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-064)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-064)

Revised: 11/2019

CLINIQUE LABORATORIES LLC