

**CLINIQUE BROAD SPECTRUM SPF 30 SUNSCREEN BODY WITH SOLAR SMART-avobenzone, homosalate, octisalate, octocrylene, and oxybenzone 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.

CLINIQUE BROAD SPECTRUM SPF 30 SUNSCREEN BODY 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 • 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 • arginine ferulate • tocopheryl acetate • caprylyl glycol • ascorbyl tocopheryl maleate • propyl gallate • stearic acid • xanthan gum • hexylene glycol • nordihydroguaiaretic acid • disodium edta • phenoxyethanol • sodium dehydroacetate • mica [iln37111]

Other information

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

PRINCIPAL DISPLAY PANEL - 150 ml Tube Carton

CLINIQUE

broad
spectrum
SPF 30
sunscreen

with
SolarSmart

UVA
UVB
PROTECTION

body cream

5 FL. OZ.
150 ml e

broad
spectrum
SPF 30
sunscreen
with
SolarSmart



INIQUE

broad
spectrum
SPF 30
sunscreen



with
SolarSmart

UVA UVB
PROTECTION

body cream

5 FL.OZ.
150 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. Shields skin against environmental aggressors with an antioxidant boost.

See enclosure,

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



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



clinique.com

6NHE-01-1117



CLINIQUE BROAD SPECTRUM SPF 30 SUNSCREEN BODY WITH SOLAR SMART

avobenzene, homosalate, octisalate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-072
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.0515 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.0278 g in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.0414 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)	
cetyl alcohol (UNII: 936JST6JCN)	
ethylhexylglycerin (UNII: 147D247K3P)	
ammonium acryloyldimethyltaurate/vp copolymer (UNII: W59H9296ZG)	
peg-8 laurate (UNII: 762O8IWA10)	
arginine ferulate (UNII: 0774Y45BEE)	
caprylyl glycol (UNII: 00YIU5438U)	
ascorbyl tocopheryl maleate (UNII: D2G6259XR5)	
propyl gallate (UNII: 8D4SNN7V92)	
stearic acid (UNII: 4ELV7Z65AP)	
xanthan gum (UNII: TTV12P4NEE)	
hexylene glycol (UNII: KEH0A3F75J)	
edetate disodium anhydrous (UNII: 8NLQ36F6MM)	
phenoxyethanol (UNII: HIE492ZZ3T)	
sodium dehydroacetate (UNII: 8W46YN971G)	
mica (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-072-01	1 in 1 CARTON	06/01/2011	
1		150 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	06/01/2011	

Labeler - CLINIQUE LABORATORIES INC. (173047747)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-072) , REPACK(49527-072)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-072)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-072)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-072)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-072)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-072) , REPACK(49527-072)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-072) , REPACK(49527-072)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-072)

Establishment

Name	Address	ID/FEI	Business Operations
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ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-072)
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Revised: 1/2019

CLINIQUE LABORATORIES INC.