

SPF 50 WITH SOLAR SMART- oxybenzone, octisalate, homosalate, avobenzene, 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.

CLINIQUE

SPF

50

face cream

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

OXYBENZONE 5.0%, OCTISALATE 5.0%, HOMOSALATE 5.0%, 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 • DI-PENTAERYTHRITYL 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 ACRYLOYLDIMETHYL TAURATE/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 [ILN37123]

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

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Carton

CLINIQUE
SPF
50
with
SolarSmart

UVA UVB
advanced
protection

face cream

1.7 FL.OZ.

50 ml e

CLINIQUE

SPF
50

with
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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
- 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

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 • ETHYLHEXYL GLYCERIN • 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 DEHY-



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

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

MICA • SODIUM BENZOATE
 DROACETATE [JLN37123]



CLINIQUE LABS., DIST.
 NEW YORK, N.Y. 10022
 LONDON W1K 3BQ • PARIS
 MADE IN U.S.A.
 6NH7



clinique.com

SPF 50 WITH SOLAR SMART

oxybenzone, octisalate, homosalate, avobenzene, and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-717
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
oxybenzone (UNII: 95OOS7VE0Y) (oxybenzone - UNII:95OOS7VE0Y)	oxybenzone	5 mL in 100 mL
octisalate (UNII: 4X49Y0596W) (octisalate - UNII:4X49Y0596W)	octisalate	5 mL in 100 mL
homosalate (UNII: V06SV4M95S) (homosalate - UNII:V06SV4M95S)	homosalate	5 mL in 100 mL
avobenzene (UNII: G63QQF2NOX) (avobenzene - UNII:G63QQF2NOX)	avobenzene	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: S73ZQI0GXM)	
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)	
dimethicone (UNII: 92RU3N3Y1O)	
glyceryl monostearate (UNII: 230OU9XXE4)	
rosemary (UNII: IJ67X351P9)	
perilla frutescens leaf (UNII: T4L5881Y68)	
caffeine (UNII: 3G6A5W338E)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	
sucrose (UNII: C151H8M554)	
cetyl alcohol (UNII: 936JST6JCN)	
ethylhexylglycerin (UNII: 147D247K3P)	
peg-8 laurate (UNII: 762O8IWA10)	
propyl gallate (UNII: 8D4SNN7V92)	
alpha-tocopherol acetate (UNII: 9E8X80D2L0)	

caprylyl glycol (UNII: 00 YIU5438U)	
stearic acid (UNII: 4ELV7Z65AP)	
xanthan gum (UNII: TTV12P4NEE)	
hexylene glycol (UNII: KEH0A3F75J)	
masoprocol (UNII: 7BO8G1BYQU)	
edetate disodium (UNII: 7FLD91C86K)	
phenoxyethanol (UNII: HIE492ZZ3T)	
mica (UNII: V8A1AW0880)	
sodium dehydroacetate (UNII: 8W46YN971G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-717-01	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	01/01/2009	

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
ARAMIS, INC		042918826	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK, RELABEL

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE

Establishment

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

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		787336577	MANUFACTURE, RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		949264774	MANUFACTURE, RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		618107429	MANUFACTURE, RELABEL, REPACK

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE