

**SUPERDEFENSE DAILY DEFENSE MOISTURIZER BROAD SPECTRUM SPF20
(COMBINATION OILY - OILY)- avobenzone and octisalate 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.

**SUPERDEFENSE DAILY DEFENSE MOISTURIZER BROAD SPECTRUM SPF20
(COMBINATION OILY - OILY)**

Drug Facts

Active ingredients

Avobenzone 3.0%

Octisalate 5.0%

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 • butyloctyl salicylate • glycerin • polyester-8 • polysorbate 60 • dimethicone • butylene

glycol • cetyl alcohol • sorbitan stearate • tridecyl stearate • peg-100 stearate • trehalose • sigesbeckia orientalis (st. paul's wort) extract • hordeum vulgare (barley) extract\extrait d'orge • triticum vulgare (wheat) germ extract • arabidopsis thaliana extract • laminaria saccharina extract • plankton extract • algae extract • sea whip extract • lactobacillus ferment • micrococcus lysate • ergothioneine • caffeine • lecithin • sodium hyaluronate • pentylene glycol • tridecyl trimellitate • dipentaerythrityl hexacaprylate/hexacaprate • tocopheryl acetate • ethylhexylglycerin • squalane • cetyl palmitate • acrylates/c10-30 alkyl acrylate crosspolymer • sorbitan palmitate • sorbitan olivate • polyethylene • sodium benzoate • ethylene/va copolymer • tetrahexyldecyl ascorbate • dimethiconol • sodium polyacrylate • sodium hydroxide • pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate • disodium edta • phenoxyethanol • chlorphenesin [iln39715]

Other information

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

PRINCIPAL DISPLAY PANEL - 50 mL Jar Carton

age prevention

C

CLINIQUE

superdefense

daily defense moisturizer

broad spectrum SPF 20

COMBINATION OILY TO OILY

POIDS NET WT. 1.7 OZ./50 ml e

age prevention



CLINIQUE

superdefense
daily defense moisturizer
broad spectrum SPF 20

COMBINATION OILY TO OILY

POIDS NET WT. 1.7 OZ./50 ml e

Allergy Tested, 100% Fragrance Free.

A smart daily defense and so refreshingly lightweight, it's a pleasure to wear every day. It starts with comfortable UVA/UVB protection. Antioxidants, of course. Then, smart ingredients that work in real time to help undo the visible effects of UV. All-day hydration strengthens skin's moisture barrier to better resist irritants. Absorbs quickly. Apply daily to face and neck before going outdoors. See enclosure.



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MADE IN U.S.A. / KE7

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SKIN TYPES
COMBINATION OILY TO OILY

CULTECH INC

004933

Drug Facts (continued)

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Drug Facts (continued)

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7KE7-01-1111

SUPERDEFENSE DAILY DEFENSE MOISTURIZER BROAD SPECTRUM SPF20 (COMBINATION OILY - OILY)

avobenzone and octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.03 g in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.05 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
glycerin (UNII: PDC6A3C0OX)	
poly sorbate 60 (UNII: CAL22UVI4M)	
dimethicone (UNII: 92RU3N3Y1O)	
butylene glycol (UNII: 3XUS85K0RA)	
cetyl alcohol (UNII: 936JST6JCN)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
tridecyl stearate (UNII: A8OE252M6L)	
peg-100 stearate (UNII: YD01N1999R)	
trehalose (UNII: B8WCK70T7I)	
wheat germ (UNII: YR3G369F5A)	
saccharina latissima (UNII: 68CMP2MB55)	
pseudopterogorgia elisabethae (UNII: UDY3H1OUX5)	
ergothioneine (UNII: BDZ3DQM98W)	
caffeine (UNII: 3G6A5W338E)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
pentylene glycol (UNII: 50C1307PZG)	
tridecyl trimellitate (UNII: FY36J270ES)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
ethylhexylglycerin (UNII: 147D247K3P)	
squalane (UNII: GW89575KF9)	
cetyl palmitate (UNII: 5ZA2S6B08X)	
sorbitan monopalmitate (UNII: 77K6Z421KU)	
sorbitan olivate (UNII: MDL271E3GR)	
high density polyethylene (UNII: UG00KM4WR7)	
sodium benzoate (UNII: OJ245FE5EU)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
sodium hydroxide (UNII: 55X04QC32I)	
pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (UNII: 255PIF62MS)	
edetate disodium (UNII: 7FLD91C86K)	
phenoxyethanol (UNII: HIE492ZZ3T)	
chlorphenesin (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-037-01	1 in 1 CARTON	10/01/2013	
1		50 mL in 1 JAR; 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	10/01/2013	

Labeler - CLINIQUE LABORATORIES LLC (044475127)**Establishment**

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-037) , REPACK(49527-037)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-037)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-037)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-037)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-037)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-037) , REPACK(49527-037)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-037) , REPACK(49527-037)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-037)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-037)

Revised: 11/2019

CLINIQUE LABORATORIES LLC