

**CLINIQUE SUPERDEFENSE AGE DEFENSE MOISTURIZER BROAD SPECTRUM SPF 25-
avobenzone, 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 SUPERDEFENSE AGE DEFENSE MOISTURIZER BROAD SPECTRUM SPF 25
COMBINATION OILY TO OILY**

Drug Facts

Active ingredients

Avobenzone 3.0%
Octisalate 5.0%
Octocrylene 1.3%
Oxybenzone 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 • dimethicone • butylene glycol • butyloctyl salicylate • isononyl isononanoate • polyester-8 • silica • glycerin • polysilicone-11 • triticum vulgare (wheat bran) extract • algae extract • laminaria saccharina extract • olea europaea (olive) fruit extract • coffea robusta seed extract • echinacea pallida (coneflower) extract • rosmarinus officinalis (rosemary) extract • sea whip extract • astrocaryum murumuru seed butter • adenosine phosphate • trehalose • disodium nadh • padina pavonica (thallus) extract • creatine • sodium rna • caffeine • micrococcus lysate • nordihydroguaiaretic acid • sodium dna • phytosphingosine • linoleic acid • cholesterol • ascorbyl tocopheryl maleate • sodium hyaluronate • aminopropyl ascorbyl phosphate • tocopheryl acetate • trisiloxane • sucrose • laurdimonium hydroxypropyl hydrolyzed soy protein • lecithin • hexylene glycol • ethylhexyl stearate • ethylhexyl palmitate • decarboxy carnosine hcl • propylene glycol dicaprate • chamomilla recutita (matricaria) • zeolite • caprylyl glycol • polyethylene • xanthan gum • laureth-4 • laureth-23 • polysorbate 20 • ammonium acryloyldimethyltaurate/vp copolymer • acrylic acid/vp crosspolymer • arginine ferulate • tromethamine • disodium edta • phenoxyethanol [iln37043]

Other information

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

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PRINCIPAL DISPLAY PANEL - 50 ml Jar Carton

CLINIQUE

superdefense

age defense moisturizer

broad spectrum SPF 25

COMBINATION OILY TO OILY

POIDS NET WT. 1.7 OZ./50 ml e



CLINIQUE

superdefense
age defense moisturizer
broad spectrum SPF 25

COMBINATION OILY TO OILY

POIDS NET WT. 1.7 OZ./50 ml e

Allergy Tested.
100% Fragrance Free.
U.S. and International Patented Technology.

Skin's most complete defense against the visible signs of aging in a daily moisturizer. Arms it to fight the visible effects of emotional stress — which research confirms damages skin, like sun and pollution. Helps neutralize UVA and UVB. Improves barrier strength. Keeps skin looking better, longer. Oil-free. See enclosure.



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Drug Facts (continued)

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NEW YORK • LONDON W1K 3BQ • PARIS
MADE IN U.S.A. 686M

clinique.com



COMBINATION ONLY TO OILY
SKIN TYPES
3,4

NC



686M011116
SD#C321922203
ED#C321922203

Drug Facts (continued)

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Drug Facts (continued)

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686M-01-1116

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avobenzone, octisalate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-709
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mL in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.3 mL in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
WHEAT BRAN (UNII: 6L966A1IMR)	
saccharina latissima thallus (UNII: 68CMP2MB55)	
BLACK OLIVE (UNII: 2M6QWV94OC)	
ROBUSTA COFFEE BEAN (UNII: V5032728L7)	
ECHINACEA PALLIDA (UNII: 904CK3270L)	
ROSEMARY (UNII: IJ67X351P9)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3HI0UX5)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
ADENOSINE PHOSPHATE (UNII: 415SHH325A)	
TREHALOSE (UNII: B8WCK70T7I)	
PADINA PAVONICA (UNII: 177U06NHZI)	
CREATINE (UNII: MU72812GK0)	
CAFFEINE (UNII: 3G6A5W338E)	
MASOPROCOL (UNII: 7BO8G1BYQU)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
AMINOPROPYL ASCORBYL PHOSPHATE (UNII: 290O2PQ83R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
SUCROSE (UNII: C151H8M554)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PROPYLENE GLYCOL DICAPRATE (UNII: U783H9JHWY)	
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

XANTHAN GUM (UNII: TTV12P4NEE)
LAURETH-4 (UNII: 6HQ855798J)
LAURETH-23 (UNII: N72LMW566G)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)
TROMETHAMINE (UNII: 023C2WHX2V)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-709-01	1 in 1 CARTON		
1		50 mL in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/01/2004	

Labeler - CLINIQUE LABORATORIES INC (173047747)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC Kabushiki Kaisha		712808195	RELABEL(49527-709) , REPACK(49527-709)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(49527-709) , RELABEL(49527-709) , REPACK(49527-709)

Establishment

Name	Address	ID/FEI	Business Operations
ARAMIS, INC		042918826	MANUFACTURE(49527-709)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(49527-709) , RELABEL(49527-709)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		253616536	MANUFACTURE(49527-709)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-709)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(49527-709)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-709)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-709)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		787336577	MANUFACTURE(49527-709) , RELABEL(49527-709) , REPACK(49527-709)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		949264774	MANUFACTURE(49527-709) , RELABEL(49527-709) , REPACK(49527-709)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		618107429	MANUFACTURE(49527-709) , RELABEL(49527-709) , REPACK(49527-709)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-709)

Establishment			
Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(49527-709)