

**CLINIQUE SKIN SUPPLIES FOR MEN AGE DEFENSE HYDRATOR BROAD SPECTRUM
SPF 15- avobenzone, octinoxate, and octisalate liquid
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
SKIN SUPPLIES FOR MEN AGE DEFENSE HYDRATOR BROAD SPECTRUM SPF 15**

Drug Facts

Active ingredients

Avobenzone 2.0%
Octinoxate 7.5%
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 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 • octyldodecyl neopentanoate • hdi/trimethylol hexyllactone crosspolymer • neopentyl glycol diheptanoate • dimethicone • silica • steareth-21 • butylene glycol • pentylene glycol • sigesbeckia orientalis (st. paul's wort) extract • rosmarinus officinalis (rosemary) extract • polyethylene • coffea robusta seed extract • polygonum cuspidatum root extract • laurdimonium hydroxypropyl hydrolyzed soy protein • saccharomyces lysate extract • steareth-2 • astrocaryum murumuru seed butter • glycerin • hydrogenated lecithin • ethylhexyl stearate • polysilicone-11 • sucrose • pvp/hexadecene copolymer • acetyl glucosamine • isohexadecane • ethylhexylglycerin • caffeine • trimethylsiloxysilicate • glyceryl polymethacrylate • acrylates/c10-30 alkyl acrylate crosspolymer • linoleic acid • cholesterol • polysorbate 80 • palmitoyl oligopeptide • ethylhexyl palmitate • tromethamine • tetrahexyldecyl ascorbate • adenosine phosphate • peg-8 • lecithin • sodium dna • arginine ferulate • acetyl hexapeptide-8 • sodium hyaluronate • phytantriol • caprylyl glycol • xanthan gum • ascorbyl tocopheryl maleate • phytosphingosine • propylene glycol dicaprate • acrylamide/sodium acryloyldimethyltaurate copolymer • hexylene glycol • nordihydroguaiaretic acid • potassium sulfate • sodium carbomer • disodium edta • sorbic acid • chlorphenesin • potassium sorbate • phenoxyethanol [iln34202]

Other information

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

PRINCIPAL DISPLAY PANEL - 50 ml Bottle Carton

CLINIQUE skin supplies for men

age defense hydrator
broad spectrum
SPF 15

hydrates, repairs, protects

ALL SKIN TYPES

1.7 FL.OZ.LIQ./50 ml e

TP 054

Allergy Tested. 100% Fragrance Free.

Comprehensive anti-aging treatment helps repair the look of lines and deeper wrinkles, defends skin against future damage with powerful antioxidants plus broad-spectrum UVA/UVB protection. Fast-absorbing formula hydrates and comforts skin all day long. Helps replenish moisture lost from shaving. Apply A.M. See enclosure.



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Drug Facts (continued)

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CLINIQUE
skin supplies
for men

age defense hydrator
broad spectrum
SPF 15

hydrates, repairs, protects

All SKIN TYPES

1.7 FL.OZ./50 ml e

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N.Y. • LONDON W1K 3RD • PARIS
MADE IN BELGIUM 69N3

clinique.com



69N3-01-1116

CLINIQUE SKIN SUPPLIES FOR MEN AGE DEFENSE HYDRATOR BROAD SPECTRUM SPF 15

avobenzone, octinoxate, and octisalate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.0203 g in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.076 g in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	0.0507 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
octyldodecyl neopentanoate (UNII: X8725R883T)	
neopentyl glycol diheptanoate (UNII: 5LKW3C543X)	
dimethicone (UNII: 92RU3N3Y1O)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
steareth-21 (UNII: 53J3F32P58)	
butylene glycol (UNII: 3XUS85K0RA)	
pentylene glycol (UNII: 50C1307PZG)	
rosemary (UNII: IJ67X351P9)	
high density polyethylene (UNII: UG00KM4WR7)	
robusta coffee bean (UNII: V5032728L7)	
polygonum cuspidatum root (UNII: 7TRV45YZF7)	
saccharomyces lysate (UNII: R85W246Z1C)	
steareth-2 (UNII: V56DFE46J5)	
astrocaryum murumuru seed butter (UNII: 12V64UPU6R)	
glycerin (UNII: PDC6A3C0OX)	
ethylhexyl stearate (UNII: EG3PA2K3K5)	
sucrose (UNII: C151H8M554)	
n-acetylglucosamine (UNII: V956696549)	
isohexadecane (UNII: 918X1OUF1E)	
ethylhexylglycerin (UNII: 147D247K3P)	
caffeine (UNII: 3G6A5W338E)	
linoleic acid (UNII: 9KJL21T0QJ)	
cholesterol (UNII: 97C5T2UQ7J)	
polyorbate 80 (UNII: 6OZP39ZG8H)	
palmitoyl oligopeptide (UNII: HO4ZT5S86C)	
ethylhexyl palmitate (UNII: 2865993309)	
tromethamine (UNII: 023C2WHX2V)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
adenosine phosphate (UNII: 415SHH325A)	

polyethylene glycol 400 (UNII: B697894SGQ)
acetyl hexapeptide-8 (UNII: L4EL31FWIL)
hyaluronate sodium (UNII: YSE9PPT4TH)
phytantriol (UNII: 8LV107A72W)
caprylyl glycol (UNII: 00YIU5438U)
xanthan gum (UNII: TTV12P4NEE)
ascorbyl tocopheryl maleate (UNII: D2G6259XR5)
phytosphingosine (UNII: GIN46U9Q2Q)
propylene glycol dicaprato (UNII: U783H9JHWY)
hexylene glycol (UNII: KEH0A3F75J)
masoprocol (UNII: 7BO8G1BYQU)
potassium sulfate (UNII: 1K573LC5TV)
edetate disodium (UNII: 7FLD91C86K)
sorbic acid (UNII: X045WJ989B)
chlorphenesin (UNII: I670DAL4SZ)
potassium sorbate (UNII: 1VPU26JZZ4)
phenoxyethanol (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-035-01	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	07/14/2010	

Labeler - CLINIQUE LABORATORIES INC. (173047747)

Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(49527-035) , REPACK(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(49527-035) , RELABEL(49527-035) , REPACK(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(49527-035) , RELABEL(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
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ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-035)
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Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(49527-035) , RELABEL(49527-035) , REPACK(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(49527-035) , RELABEL(49527-035) , REPACK(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(49527-035) , RELABEL(49527-035) , REPACK(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(49527-035)

Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(49527-035) , RELABEL(49527-035)