

PEP START HYDRORUSH MOISTURIZER BROAD SPECTRUM SPF 20- 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.

PEP START HYDRORUSH MOISTURIZER BROAD SPECTRUM SPF 20

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 resistance 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 • pentylene glycol • sigesbeckia orientalis

(st. paul's wort) extract • laminaria saccharina extract • plankton extract • arabidopsis thaliana extract • lactobacillus ferment • ergothioneine • palmitoyl tetrapeptide-7 • sea whip extract • hordeum vulgare (barley) extract\extrait d'orge • caffeine • algae extract • squalane • ethylhexylglycerin • trehalose • palmitoyl tripeptide-1 • triticum vulgare (wheat) germ extract • micrococcus lysate • tridecyl trimellitate • tocopheryl acetate • dipentaerythrityl hexacaprylate/hexacaprate • peg-100 stearate • acrylates/c10-30 alkyl acrylate crosspolymer • cetyl palmitate • sorbitan palmitate • sorbitan olivate • sodium benzoate • ethylene/va copolymer • dimethiconol • tetrahexyldecyl ascorbate • sodium hydroxide • sodium polyacrylate • polyethylene • lecithin • sodium hyaluronate • carbomer • polysorbate 20 • disodium edta • pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate • bht • chlorphenesin • phenoxyethanol
[iln42436]

Other information

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

PRINCIPAL DISPLAY PANEL - 50 ml Jar Carton

CLINIQUE

pep-start

hydrorush moisturizer

broad spectrum

SPF 20

NET WT. 1.7 OZ./50 ml e

ALL SKIN TYPES
TOUS TYPES DE PEAU

1, 2, 3, 4

CLINIQUE
pep-start

hydrorush moisturizer
broad spectrum
SPF 20

POIDS NET WT. 1.7 OZ./50 ml e

Allergy Tested. 100% Fragrance Free.

Instantly refreshing formula with HydroRush moisture barrier technology. Hydrates all day. Provides UV protection. And skin's ready to face the day. Non-acnegenic.

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avobenzone and octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49527-054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
glycerin (UNII: PDC6A3C0OX)	
polyester-8 (1400 mw, cyanodiphenylpropenoyl capped) (UNII: T9296U138P)	
polysorbate 60 (UNII: CAL22UVI4M)	
dimethicone (UNII: 92RU3N3Y1O)	
butylene glycol (UNII: 3XUS85K0RA)	
cetyl alcohol (UNII: 936JST6JCN)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
tridecyl stearate (UNII: A8OE252M6L)	
pentylene glycol (UNII: 50C1307PZG)	
saccharina latissima (UNII: 68CMP2MB55)	
arabidopsis thaliana (UNII: A13L60HQ81)	
lactobacillus reuteri (UNII: 9913I24QEE)	
ergothioneine (UNII: BDZ3DQM98W)	
palmitoyl tetrapeptide-7 (UNII: Q41S464P1R)	
pseudopterogorgia elisabethae (UNII: UDY3H1OUX5)	
barley (UNII: 5PWM7YLI7R)	
caffeine (UNII: 3G6A5W338E)	
squalane (UNII: GW89575KF9)	
ethylhexylglycerin (UNII: 147D247K3P)	
trehalose (UNII: B8WCK70T7I)	
palmitoyl tripeptide-1 (UNII: RV743D216M)	
wheat germ (UNII: YR3G369F5A)	
tridecyl trimellitate (UNII: FY36J270ES)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
peg-100 stearate (UNII: YD01N1999R)	
carbomer interpolymer type a (allyl sucrose crosslinked) (UNII: 59TL3WG5CO)	
cetyl palmitate (UNII: 5ZA2S6B08X)	
sorbitan monopalmitate (UNII: 77K6Z421KU)	
sorbitan olivate (UNII: MDL271E3GR)	
sodium benzoate (UNII: OJ245FE5EU)	
tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)	
sodium hydroxide (UNII: 55X04QC32I)	
high density polyethylene (UNII: UG00KM4WR7)	
hyaluronate sodium (UNII: YSE9PPT4TH)	
carboxypolymethylene (UNII: 0A5MM307FC)	
polysorbate 20 (UNII: 7T1F30V5YH)	
edetate disodium anhydrous (UNII: 8NLQ36F6MM)	
pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) (UNII: 255PIF62MS)	

butylated hydroxytoluene (UNII: 1P9D0Z171K)	
chlorphenesin (UNII: I670DAL4SZ)	
phenoxyethanol (UNII: HIE492ZZ3T)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49527-054-01	1 in 1 CARTON	09/01/2016	
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	09/01/2016	

Labeler - CLINIQUE LABORATORIES LLC (044475127)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(49527-054) , REPACK(49527-054)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(49527-054)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(49527-054)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(49527-054)

Establishment			
Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(49527-054)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(49527-054) , REPACK(49527-054)

Establishment			
Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(49527-054) , REPACK(49527-054)

Establishment			
Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(49527-054)

Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(49527-054)

Revised: 11/2019

CLINIQUE LABORATORIES LLC