

PLANTSCRIPTION SPF 25 POWER ANTI AGING BROAD SPECTRUM 25- avobenzone, homosalate, octisalate, and octocrylene cream
ORIGINS NATURAL RESOURCES 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.

PLANTSCRIPTION™ SPF 25 POWER ANTI AGING CREAM BROAD SPECTRUM 25

Drug Facts

Active ingredients	Purpose
avobenzone 3.0%	Sunscreen
homosalate 5.0%	Sunscreen
octisalate 4.5%	Sunscreen
octocrylene 2.8%	Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**) decreases the risk of skin cancer and early skin aging caused by the sun

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 generously and evenly 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 10am – 2pm
 - wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

Inactive ingredients

water\agua\ea • butyloctyl salicylate • nylon-12 • behenyl alcohol • octyldodecyl neopentanoate • myristyl myristate • dimethicone • cetyl esters • polyethylene • butylene glycol • ammonium acryloyldimethyltaurate/vp copolymer • glycerin • rosa damascena flower oil¹, lavandula angustifolia

(lavender) oil¹, pelargonium graveolens flower oil¹, illicium verum (anise) fruit/seed oil¹, citrus aurantium bergamia (bergamot) fruit oil¹, carthamus tinctorius (safflower) seed oil¹, myristica fragrans (nutmeg) kernel oil¹, citrus aurantium dulcis (orange) peel oil¹, citrus nobilis (mandarin orange) peel oil¹, citrus limon (lemon) peel oil¹, litsea cubeba fruit oil¹, hibiscus abelmoschus extract, geraniol, linalool, citronellol, limonene, citral • peg-6 • peg-100 stearate • glyceryl stearate • caprylic/capric triglyceride • hydrogenated vegetable oil • steareth-21 • anogeissus leiocarpus bark extract • sigesbeckia orientalis (st. paul's wort) extract • centaurium erythraea (centaury) extract • rubus idaeus (raspberry) leaf extract • rosmarinus officinalis (rosemary) leaf extract • triticum vulgare (wheat) germ extract • hordeum vulgare (barley) extract\extrait d'orge • bambusa vulgaris (bamboo) extract • peucedanum graveolens (dill) extract • coffea arabica (coffee) seed extract • laminaria digitata extract • trehalose • cassia alata leaf extract • tetrahexyldecyl ascorbate • sodium hyaluronate • caffeine • acetyl hexapeptide-8 • di-ppg-2 myreth-10 adipate • caprylyl glycol • micrococcus lysate • lecithin • trisiloxane • linoleic acid • phytosphingosine • ethylhexylglycerin • sodium pca • squalane • glucosamine hcl • pisum sativum (pea) extract • crithmum maritimum extract • tocopheryl acetate • hydrolyzed algin • sodium dehydroacetate • maltodextrin • hexylene glycol • citric acid • potassium sorbate • disodium edta • phenoxyethanol • mica <iln43907>

¹ essential oil

Other information

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

PRINCIPAL DISPLAY PANEL - 50 ml Jar Carton

ORIGINS

PLANTSCRIPTION™

SPF 25

Power Anti-Aging

Cream

Broad Spectrum SPF 25

net wt. 1.7 oz./50 ml e



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OLR5011113 6620

Drug Facts (continued)

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 - wear long-sleeved shirts, pants, hats and sunglasses
 - children under 6 months of age: ask a doctor

Inactive ingredients: water/aqua/eau • butyl/octyl salicylate • nylon-12 • behenyl alcohol • octyldodecyl neopentanoate • myristyl myristate • dimethicone • cetyl esters • polyethylene • butylene glycol • ammonium acryloyldimethyltaurate/vp copolymer • glycerin • rosa damascena flower oil*, lavandula angustifolia (lavender) oil*, pelargonium graveolens flower ►

Drug Facts (continued)

oil*, illicium verum (anise) fruit/seed oil*, citrus aurantium bergamia (bergamot) fruit oil*, carthamus tinctorius (safflower) seed oil*, myristica fragans (nutmeg) kernel oil*, citrus aurantium dulcis (orange) peel oil*, citrus nobilis (mandarin orange) peel oil*, citrus limon (lemon) peel oil*, litssea cubeba fruit oil*, hibiscus sabdariffa extract, geraniol, linalool, citronellol, limonene, citral, peg-6, peg-10 stearate, glyceryl stearate, caprylic/capric triglyceride, hydrogenated vegetable oil, steareth-21, anogeissus leiocarpus bark extract, sagesbeckia orientalis (st. paul's wort) extract, centaurium erythraea (centaury) extract, rubus idaeus (raspberry) leaf extract, rosmarinus officinalis (rosemary) leaf extract, triticum vulgare (wheat) germ extract, hordeum vulgare (barley) extract, extract d'orge, bambusa vulgaris (bamboo) extract, peucedanum graveolens (dill) extract, coffee arabica (coffee) seed extract, laminaria digitata extract, trehalose, cassia alata leaf extract, tetrahexyldecyl ascorbate, sodium hyaluronate, caffeine, acetyl hexapeptide-8, di-pgg-2 myreth-10 adipate, caprylic/glycol, micrococcus lysate, lecithin, trisiloxane, linoleic acid, phytosphingosine, ethylhexylglycerin, sodium pca, squalane, glucosamine hydrochloride, pismum sativum (pea) extract, crithmum maritimum extract, tocopheryl acetate, hydrolyzed algin, sodium dehydroacetate, maltodextrin, hexylene glycol, citric acid, potassium sorbate, disodium edta, phenoxyethanol, mica <ln43907>, *essential oil

Other information

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



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New York • London • Paris
Made in USA #OLR5
origins.com



OLR5-01-1113

PLANTSCRIPTION SPF 25 POWER ANTI AGING BROAD SPECTRUM 25

avobenzone, homosalate, octislate, and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59427-114
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
nylon-12 (UNII: 446U8J075B)	
docosanol (UNII: 9G1OE216XY)	
octyldodecyl neopentanoate (UNII: X8725R883T)	
myristyl myristate (UNII: 4042ZC00DY)	
dimethicone (UNII: 92RU3N3Y1O)	
cetyl esters wax (UNII: D072FFP9GU)	
high density polyethylene (UNII: UG00KM4WR7)	
butylene glycol (UNII: 3XUS85K0RA)	
ammonium acryloyldimethyltaurate/vp copolymer (UNII: W59H9296ZG)	
glycerin (UNII: PDC6A3C0OX)	
rosa x damascena flower oil (UNII: 18920M3T13)	
lavender oil (UNII: ZBP1YXW0H8)	
pelargonium graveolens flower oil (UNII: 3K0J1S7QGC)	
anise (UNII: 21C2F5E8RE)	
bergamot oil (UNII: 39W1PKE3JI)	
safflower oil (UNII: 65UEH262IS)	
nutmeg oil (UNII: Z1CLM48948)	
orange oil (UNII: AKN3KSD11B)	
mandarin oil (UNII: NJO720F72R)	
lemon oil (UNII: I9GRO824LL)	
litsea oil (UNII: 2XIW34BN6O)	
geraniol (UNII: L837108USY)	
linalool, (+/-)- (UNII: D81QY6188E)	
.beta.-citronellol, (r)- (UNII: P01OUT964K)	
citral (UNII: T7EU0O9VPP)	
polyethylene glycol 300 (UNII: 5655G9Y8AQ)	
peg-100 stearate (UNII: YD01N1999R)	
glyceryl monostearate (UNII: 230OU9XXE4)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
steareth-21 (UNII: 53J3F32P58)	
centaurium erythraea (UNII: 57X4TSH58S)	
raspberry (UNII: 4N14V5R27W)	
rosemary (UNII: IJ67X351P9)	
wheat (UNII: 4J2I0SN84Y)	
barley (UNII: 5PWM7YLI7R)	
dill (UNII: Y05PC4JZRH)	
trehalose (UNII: B8WCK70T7I)	

tetrahexyldecyl ascorbate (UNII: 9LBV3F07AZ)
hyaluronate sodium (UNII: YSE9PPT4TH)
caffeine (UNII: 3G6A5W338E)
acetyl hexapeptide-8 (UNII: L4EL31FWIL)
di-ppg-2 myreth-10 adipate (UNII: 4IN301M0KJ)
caprylyl glycol (UNII: 00YIU5438U)
trisiloxane (UNII: 9G1ZW13R0G)
linoleic acid (UNII: 9KJL21T0QJ)
phytosphingosine (UNII: GIN46U9Q2Q)
ethylhexylglycerin (UNII: 147D247K3P)
sodium pyrrolidone carboxylate (UNII: 469OTG57A2)
squalane (UNII: GW89575KF9)
glucosamine hydrochloride (UNII: 750W5330FY)
pea (UNII: W4X7H8GYFM)
sodium dehydroacetate (UNII: 8W46YN971G)
malto dextrin (UNII: 7CVR7L4A2D)
hexylene glycol (UNII: KEH0A3F75J)
citric acid monohydrate (UNII: 2968PHW8QP)
potassium sorbate (UNII: 1VPU26JZZ4)
edetate disodium anhydrous (UNII: 8NLQ36F6MM)
phenoxyethanol (UNII: HIE492ZZ3T)
mica (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59427-114-01	1 in 1 CARTON	01/01/2017	
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	01/01/2017	

Labeler - ORIGINS NATURAL RESOURCES INC. (611716283)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(59427-114) , REPACK(59427-114)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(59427-114)

Establishment

Name	Address	ID/FEI	Business Operations

ESTEE LAUDER COSMETICS, LTD.	202952982	MANUFACTURE(59427-114)
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Establishment			
Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(59427-114)

Establishment				
Name		Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC			809771152	MANUFACTURE(59427-114)

Establishment			
Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(59427-114) , REPACK(59427-114)

Establishment			
Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(59427-114) , REPACK(59427-114)

Establishment				
Name		Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.			216866277	MANUFACTURE(59427-114)

Establishment				
Name		Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD			255175580	MANUFACTURE(59427-114)

Revised: 1/2019

ORIGINS NATURAL RESOURCES INC.