

**BRIGHTER BY NATURE SPF 35 SKIN TONE CORRECTING MOISTURIZER BROAD SPECTRUM- homosalate, octisalate, avobenzone, 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.*

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**BRIGHTER BY NATURE™**  
**SPF 35 SKIN TONE CORRECTING MOISTURIZER BROAD SPECTRUM**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
avobenzone 3.00%	Sunscreen
homosalate 5.00%	Sunscreen
octisalate 5.00%	Sunscreen
octocrylene 2.70%	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 • methyl trimethicone • jojoba esters • polyester-8 • ethyl macadamiate • butylene glycol • lauryl peg-9 polydimethylsiloxyethyl dimethicone • peg-100 stearate •

butyrospermum parkii (shea butter) • glyceryl stearate • citrus aurantifolia (lime) oil<sup>1</sup>, citrus grandis (grapefruit) peel oil<sup>1</sup>, cymbopogon schoenanthus oil<sup>1</sup>, mentha viridis (spearmint) leaf oil<sup>1</sup>, salvia sclarea (clary) oil<sup>1</sup>, ormenis multicaulis oil<sup>1</sup>, pelargonium graveolens flower oil<sup>1</sup>, lavandula angustifolia (lavender) oil<sup>1</sup>, thymus vulgaris (thyme) oil<sup>1</sup>, coriandrum sativum (coriander) fruit oil<sup>1</sup>, citral, geraniol, linalool, citronellol, limonene • gentiana lutea (gentian) root extract • hordeum vulgare (barley) extract\extrait d'orge • paeonia albiflora (peony) root extract • sanguisorba officinalis (burnet) root extract • cucumis sativus (cucumber) fruit extract • perilla ocymoides leaf extract • pyrus malus (apple) fruit extract • hydrolyzed rice bran extract • scutellaria baicalensis root extract • triticum vulgare (wheat) germ extract • polygonum tinctorium leaf/stem extract • curcuma longa (turmeric) root extract • palmaria palmata extract • trametes versicolor extract • micrococcus lysate • mangifera indica (mango) seed butter • silica • potassium cetyl phosphate • cetyl alcohol • ethylhexylglycerin • arginine • ascorbyl glucoside • caffeine • lecithin • phytosterols • salicylic acid • cholesterol • behenyl alcohol • tocotrienols • linoleic acid • sodium hyaluronate • squalane • magnesium ascorbyl phosphate • elaeis guineensis (palm) oil • squalene • phospholipids • ammonium acryloyldimethyltaurate/vp copolymer • caprylyl glycol • tocopheryl acetate • glycyrrhetic acid • dehydroxanthan gum • sodium hydroxide • tocopherol • stearic acid • sodium dehydroacetate • phenoxyethanol • mica <iln38194>

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<sup>1</sup> essential oil

## Other information

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

## PRINCIPAL DISPLAY PANEL - 50 ml Jar Carton

### ORIGINS

**Brighter By Nature™ SPF 35**

Skin tone correcting moisturizer

Broad Spectrum SPF 35

net wt. 1.7 oz./50 ml e

### **Formulated without:**

- Parabens • Phthalates • Propylene Glycol
- Mineral Oil • PABA • Petrolatum • Paraffin
- DEA • Synthetic Color • Synthetic Fragrance
- Animal Ingredients

Origins tests its products on volunteer panels.  
For more information visit: [www.origins.com](http://www.origins.com)

Carton made from 50% post-consumer recycled fiber. Paperboard and carton manufactured using only wind power or hydropower, both renewable energy resources. Please recycle where available.



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## BRIGHTER BY NATURE SPF 35 SKIN TONE CORRECTING MOISTURIZER BROAD SPECTRUM

homosalate, octisalate, avobenzene, and octocrylene cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:59427-008

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	0.0498 g in 1 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	0.0498 g in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.02988 g in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.02689 g in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>water</b> (UNII: 059QF0KO0R)	
<b>butyloctyl salicylate</b> (UNII: 2EH13UN8D3)	
<b>methyl trimethicone</b> (UNII: S73ZQI0GXH)	
<b>ethyl macadamiate</b> (UNII: ANA2NCS6V1)	
<b>butylene glycol</b> (UNII: 3XUS85K0RA)	
<b>lauryl peg-9 polydimethylsiloxyethyl dimethicone</b> (UNII: 25G622K2RA)	
<b>peg-100 stearate</b> (UNII: YD01N1999R)	
<b>shea butter</b> (UNII: K49155WL9Y)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>lime oil</b> (UNII: UZH29XGA8G)	
<b>citrus maxima fruit rind oil</b> (UNII: 8U3877WD44)	
<b>cymbopogon schoenanthus oil</b> (UNII: XE7K568ILO)	
<b>spearmint oil</b> (UNII: C3M81465G5)	
<b>clary sage oil</b> (UNII: 87L0D4U3M0)	
<b>pelargonium graveolens flower oil</b> (UNII: 3K0J1S7QGC)	
<b>lavender oil</b> (UNII: ZBP1YXW0H8)	
<b>thyme oil</b> (UNII: 2UK410MY6B)	
<b>coriander oil</b> (UNII: 7626GC95E5)	
<b>citral</b> (UNII: T7EU0O9VPP)	
<b>geraniol</b> (UNII: L837108USY)	
<b>linalool, (+/-)-</b> (UNII: D81QY6I88E)	
<b>.beta.-citronellol, (r)-</b> (UNII: P01OUT964K)	
<b>gentiana lutea root</b> (UNII: S72O3284MS)	
<b>paeonia lactiflora root</b> (UNII: 3Z3866YW6P)	
<b>sanguisorba officinalis root</b> (UNII: 4NYV2HT01X)	
<b>cucumber</b> (UNII: YY7C30VXJT)	
<b>perilla frutescens top</b> (UNII: T4L5881Y68)	
<b>apple</b> (UNII: B423VGH5S9)	
<b>scutellaria baicalensis root</b> (UNII: 7J95K7ID2S)	
<b>wheat germ</b> (UNII: YR3G369F5A)	
<b>persicaria tinctoria top</b> (UNII: 4D6LH3E17E)	
<b>turmeric</b> (UNII: 856YO1Z64F)	
<b>dulse</b> (UNII: 7832HOY4ZQ)	
<b>mangifera indica seed butter</b> (UNII: 40XD9M35X2)	
<b>silicon dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>potassium cetyl phosphate</b> (UNII: 03KCY6P7UT)	
<b>cetyl alcohol</b> (UNII: 936JST6JCN)	

ethylhexylglycerin (UNII: 147D247K3P)
arginine (UNII: 94ZLA3W45F)
ascorbyl glucoside (UNII: 2V52R0NHXW)
caffeine (UNII: 3G6A5W338E)
salicylic acid (UNII: O414PZ4LPZ)
cholesterol (UNII: 97C5T2UQ7J)
docosanol (UNII: 9G1OE216XY)
tocotrienols (UNII: KP2MW85SSQ)
linoleic acid (UNII: 9KJL21T0QJ)
hyaluronate sodium (UNII: YSE9PPT4TH)
squalane (UNII: GW89575KF9)
magnesium ascorbyl phosphate (UNII: 0R822556M5)
palm oil (UNII: 5QU005548Z)
squalene (UNII: 7QWM220FJH)
ammonium acryloyldimethyltaurate/vp copolymer (UNII: W59H9296ZG)
caprylyl glycol (UNII: 00YIU5438U)
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)
enoxolone (UNII: P540XA09DR)
sodium hydroxide (UNII: 55X04QC32I)
tocopherol (UNII: R0ZB2556P8)
stearic acid (UNII: 4ELV7Z65AP)
sodium dehydroacetate (UNII: 8W46YN971G)
phenoxyethanol (UNII: HIE492ZZ3T)
mica (UNII: V8A1AW0880)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59427-008-01	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	10/01/2010	

**Labeler** - ORIGINS NATURAL RESOURCES INC. (611716283)

## Establishment

Name	Address	ID/FEI	Business Operations
ELGC K.K.		712808195	RELABEL(59427-008) , REPACK(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
Estee Lauder Pennsylvania Distribution Center 2 (PADC 2)		828534516	MANUFACTURE(59427-008) , RELABEL(59427-008) , REPACK(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS DISTRIBUTION CENTER		208579636	REPACK(59427-008) , RELABEL(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		205952385	MANUFACTURE(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V.		370151326	MANUFACTURE(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTEC KEYSTONE		943871157	MANUFACTURE(59427-008) , RELABEL(59427-008) , REPACK(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC BRISTOL		959338336	MANUFACTURE(59427-008) , RELABEL(59427-008) , REPACK(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC KEYSTONE		949264774	MANUFACTURE(59427-008) , RELABEL(59427-008) , REPACK(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
Aveda Corporation		071352058	MANUFACTURE(59427-008)

## Establishment

Name	Address	ID/FEI	Business Operations
Pennsylvania Logistics Center		078364654	REPACK(59427-008) , RELABEL(59427-008)