

DR WEILS MEGA-DEFENSE ADVANCED DAILY UV DEFENDER BROAD SPECTRUM SPF 45 SUNCREEN- titanium dioxide and zinc oxide lotion
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.

DR WEILS MEGA-DEFENSE ADVANCED DAILY UV DEFENDER BROAD SPECTRUM SPF 45 SUNCREEN

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
titanium dioxide 6.3%	Sunscreen
zinc oxide 4.0%	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/aqua/eau • dimethicone • butyloctyl salicylate • c12-15 alkyl benzoate • methyl trimethicone • isononyl isononanoate • diethylhexyl succinate • neopentyl glycol diheptanoate • butylene glycol • dipentaerythrityl tri-polyhydroxystearate • lauryl peg-9 polydimethylsiloxylethyl dimethicone • silica •

citrus aurantium dulcis (orange) peel oil¹, pelargonium odorata flower oil¹, eugenia caryophyllus (clove) bud oil¹, rosa damascena flower oil¹, jasminum officinale (jasmine) oil¹, viola odorata flower/leaf extract, polianthes tuberosa extract, geraniol, benzyl benzoate, citronellol, eugenol • epilobium angustifolium flower/leaf/stem extract • hordeum vulgare (barley) extract/extrait d'orge • triticum vulgare (wheat) germ extract • vaccinium angustifolium (blueberry) fruit extract • vaccinium macrocarpon (cranberry) fruit extract • lycium chinense (wolfberry) fruit extract • rosa roxburghii fruit extract • opuntia tuna extract • trimethylsiloxysilicate • hydroxyapatite • cetyl peg/ppg-10/1 dimethicone • glycerin • scutellaria baicalensis root extract • squalane • yeast extract/extrait de levure • dimethicone/peg-10/15 crosspolymer • dimethicone silylate • tocopheryl acetate • hydrolyzed wheat protein/pvp crosspolymer • dimethicone crosspolymer-3 • isostearic acid • caprylyl glycol • polyhydroxystearic acid • bht • phenoxyethanol <iln41804>

¹ essential oil

Other information

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

PRINCIPAL DISPLAY PANEL - 30 ml Bottle Carton

Dr. Andrew

WEIL for Origins™

Mega-Defense

SPF 45

Advanced Daily

UV Defender

Broad Spectrum SPF 45

1 fl. oz./oz. liq./30 ml e



**Advanced Daily
UV Defender
Broad Spectrum
SPF 45**

♻️ Cuton made from 50% recycled paper, cardboard and cotton fiber. Paperboard and cotton manufacturers using only wind power or hydropower, both renewable energy resources. ♻️ Please recycle where available.

Dr. Andrew
WEIL for Origins™

Here's powerful 3-tier daily protection against the skin-damaging effects of pollution, dehydration and environmental stress. Our potent formula with *Opuntia ficus-indica* helps shield skin against harmful UVA/UVB rays, ward off skin damage and strengthen skin's barrier to help minimize the negative impact of pollution on skin and defend it against future aggressors and discolorations. 100% non-chemical sunscreen. Andrew Weil, M.D., donates all of his after-tax profits from royalties from sales of our products directly to the Weil Foundation. For more information, visit: www.weilfoundation.org. Dr. Andrew Weil™ Trademark Under License

**Mega-Defense
SPF 45**
Advanced Daily
UV Defender
Broad Spectrum SPF 45
1 fl.oz./oz. liq./30 ml e



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Drug Facts (continued)

Inactive ingredients: water/aqua/eau • dimethicone • butyloctyl salicylate • c12-15 alkyl benzoate • methyl trimethicone • isononyl isononanoate • diethylhexyl succinate • neopentyl glycol diheptanoate • butylene glycol • dipentaerythrityl tri-polyhydroxystearate • lauryl peg-8 polydimethylsiloxyethyl dimethicone • silica • citrus aurantium dulcis (orange) peel oil*, pelargonium odorata flower oil*, eugenia caryophyllus (clove) bud oil*, rosa damascena flower oil*, jasminum officinale (jasmimine) oil*, viola odorata flower/leaf extract, polianthes tuberosa extract, geraniol, benzyl benzoate, citronellol, eugenol • epilobium angustifolium flower/leaf stem extract • hordeum vulgare (barley) extract/extrait d'orge • triticum vulgare (wheat) germ extract • vaccinium angustifolium (blueberry) fruit extract • vaccinium macrocarpon (cranberry) fruit extract • lycium chinense (wolfberry) fruit extract • rosa roxburghii fruit extract • opuntia tuna extract • trimethylsiloxyethyl silicate • hydroxyapatite • cetyl peg/ppg-10/1 dimethicone • glycerin • scutellaria baicalensis root extract • squalane • yeast extract/faex/extrait de levure • dimethicone/peg-10/15 crosspolymer • dimethicone silylate • tocopheryl acetate • hydrolyzed wheat protein/pvp crosspolymer • dimethicone crosspolymer • 3 isostearic acid • caprylyl glycol • polyhydroxystearic acid • bht • phenoxyethanol <ln41804> *essential oil

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DR WEIL'S MEGA-DEFENSE ADVANCED DAILY UV DEFENDER BROAD SPECTRUM SPF 45 SUNSCREEN

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59427-113
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	66.78 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.96 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIPENTAERYTHRITYL TRI-POLYHYDROXYSTEARATE (UNII: D21K655H52)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ORANGE OIL (UNII: AKN3KSD11B)	
CLOVE OIL (UNII: 578389D6D0)	
ROSA X DAMASCENA FLOWER OIL (UNII: 18920M3T13)	
JASMINUM OFFICINALE FLOWER (UNII: 0Q8K841432)	
VIOLA ODORATA FLOWERING TOP (UNII: 04BPC8714H)	
GERANIOL (UNII: L837108USY)	
BENZYL BENZOATE (UNII: N863NB338G)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
EUGENOL (UNII: 3T8H1794QW)	
EPILOBIUM ANGUSTIFOLIUM FLOWERING TOP (UNII: 08H094218D)	
BARLEY (UNII: 5PWM7YL17R)	
WHEAT GERM (UNII: YR3G369F5A)	
LOWBUSH BLUEBERRY (UNII: G90PX41VP0)	
CRANBERRY (UNII: 0MVO31Q3QS)	
LYCIUM CHINENSE FRUIT (UNII: TG711Q7A1Q)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
GLYCERIN (UNII: PDC6A3C0OX)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
SQUALANE (UNII: GW89575KF9)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISO STEARIC ACID (UNII: X33R8U0062)	
CAPRYL YL GLYCOL (UNII: 00YIU5438U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59427-113-01	1 in 1 CARTON	02/15/2016	
1		30 mL in 1 BOTTLE; 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	02/15/2016	

Labeler - ORIGINS NATURAL RESOURCES INC. (611716283)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COMPANY, THE		828534516	RELABEL(59427-113) , REPACK(59427-113)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		244669714	MANUFACTURE(59427-113)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD.		202952982	MANUFACTURE(59427-113)

Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER N.V		370151326	MANUFACTURE(59427-113)

Establishment

Name	Address	ID/FEI	Business Operations
LEN-RON MANUFACTURING DIVISION OF ARAMIS INC		809771152	MANUFACTURE(59427-113)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHTEC INC		943871157	RELABEL(59427-113) , REPACK(59427-113)

Establishment

Name	Address	ID/FEI	Business Operations
PADC 1		949264774	RELABEL(59427-113) , REPACK(59427-113)

Establishment

Name	Address	ID/FEI	Business Operations
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WHITMAN LABORATORIES, LTD.		216866277	MANUFACTURE(59427-113)
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Establishment

Name	Address	ID/FEI	Business Operations
ESTEE LAUDER COSMETICS, LTD		255175580	MANUFACTURE(59427-113)

Revised: 12/2018

ORIGINS NATURAL RESOURCES INC.