# ILLUMINATING DAILY MOISTURIZER- avobenzone, octisalate and octocrylene cream Topco Associates 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.

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#### TopCare® Illuminating Daily Moisturizer Broad Spectrum SPF15 Sunscreen

#### **Active ingredient**

Avobenzone 3.0% Octisalate 5.0% Octocrylene 8.0%

### Purpose

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 swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Apply liberally 15 minutes before sun exposure.
- Children under 6 months of age: ask a doctor
- **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

#### Other Information

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

#### **Inactive ingredients**

water, C12-15 alkyl benzoate, arachidyl alcohol, behenyl alcohol, arachidyl glucoside, cetearyl alcohol, cetearyl glucoside, steareth-2, glycerin, steareth-21, dimethicone, phenyl trimethicone, polyacrylamide, C13-14 isoparaffin, laureth-7, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, panthenol, polymethyl methacrylate, lecithin, soy isoflavones, polysorbate 80, alcohol, benzyl alcohol, disodium EDTA, fragrance, benzalkonium chloride, BHT, triethanolamine

#### Questions?

1-888-423-0139

#### Package/Label Principal Display Panel

**TopCare**® Illuminating Daily Moisturizer Broad Spectrum SPF15 Sunscreen

Clinically proven

Evens out skin tone and texture with an exclusive soy complex and light diffusers

\*compare to Aveeno® Positively Radiant  $^{TM}$ 

4 FL OZ (120 mL)

DISTRIBUTED BY TOPCO ASSOCIATES LLC 7711 GROSS POINT ROAD SKOKIE, IL 60077 ©TOPCO PER1109 QUESTIONS? 1-888-423-0139 topcare@topco.com

Manufactured in Israel 52326 88 C2

#### Illuminating Daily Moisturizer Broad Spectrum SPF15 Sunscreen TopCare. This unique moisturizer has Oil-Free • Hypoallergenic • Non-Comedogenic an exclusive soy complex and light diffusers that work together to naturally even out skin tone and **Drug Facts** texture, immediately reflecting light to visibly Active ingredients Purpose smooth skin imperfections, Avobenzone 3.0% bringing out skin's natural octisalate 5.0%.. Octocrylene 8.09 Sunscreen Sunscreen radiance. This light and quickly absorbed moisturizer is gentle 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 enough for sensitive skin to help maintain healthy-looking skin. Warnings For external use only. Illuminating Daily Do not use on • damaged or broken skin. Moisturizer Broad When using this product • keep out of eyes. Rinse with water Spectrum SPF15 Sunscreen is clinically proven to: Stop use and ask a doctor . if rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. · Leave smoother skin · Improve skin's tone and texture Apply liberally 15 minutes before sun exposure. Apply liberally 15 minutes before sun exposure. Children under 6 months of age: ask a doctor 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. · Visibly even out discolorations · Improve skin's



**Carton Label** 

radiance

\*This product is not manufactured or distributed by Johnson & Johnson, owner

of the registered trademark Aveeno® Positively Radiant™

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Manufactured in Israel

#### ILLUMINATING DAILY MOISTURIZER

avobenzone, octisalate and octocrylene cream

measures including:

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Other Information • protect the product in this contains from excessive heat and direct sun

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-339
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	5 mL in 100 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 mL in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	

DOCOSANOL (UNII: 9G10E216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCO SIDE (UNII: 09 FUA47KNA)	
STEARETH-2 (UNII: V56DFE46J5)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARETH-21 (UNII: 53J3F32P58)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NO J4R)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
ETHYLPARABEN (UNII: 14255EXE39)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYLPARABEN (UNII: 0 QQJ25X58G)	
PANTHENOL (UNII: WV9CM0O67Z)	
POLY(METHYL ACRYLATE-CO-METHYL METHACRYLATE-CO-METHACRYLIC ACID 7:3:1; 280000 MW) (UNII: 99Q3C7L77T)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
SOY ISOFLAVONES (UNII: 71B37NR06D)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BUTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K)	
TROLAMINE (UNII: 903K93S3TK)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800-339-19	1 in 1 CARTON			
1		120 mL in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/11/2012	

## Labeler - Topco Associates LLC (006935977)

Revised: 5/2012 Topco Associates LLC