# LONG-LASTING OIL-FREE MOISTURIZER- avobenzone, octisalate, octocrylene and oxybenzone 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.

-----

# TopCare® Long Lasting Oil-Free Moisturizer Broad Spectrum SPF15 Sunscreen for Face

# Active ingredient

Avobenzone 2.0% Octisalate 5.0% Octocrylene 4.0% Oxybenzone 3.0%

# **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, carbomer, cetearyl alcohol, ceteareth-20, glycerin, c12-15 alkyl benzoate, glyceryl stearate, peg-100 stearate, diisopropyl adipate, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, dimethicone, triethanolamine

Questions?

1-888-423-0139

# Package/Label Principal Display Panel

TopCare Long Lasting Oil-Free Moisturizer Broad Spectrum SPF15 Sunscreen For FACE

Hypoallergenic Non-comedogenic Dermatologist tested

SPF 15

\*compare to Neutrogena® Oil-Free Moisture SPF 15 Ingredients With Broad Spectrum sun protection

4 FL OZ (118mL)

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 82026 88 C2

# Top Care.

()il-Free Moisturizer **Broad Spectrum** SPF15 Sunscreen

# **Drug Facts**

Active ingredients	Purpose
Avobenzone 2.0%	Sunscreen
	Sunscreen
Octocrylene, 4.0%	Sunscreen
Oxybenzone, 3.0%	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

#### 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

#### 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, carbomer, cetearyl alcohol, ceteareth-20, glycerin, C12-15 alkyl benzoate, glyceryl stearate, PEG-100 stearate, diiosopropyl adipate, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, diiosthicae, triathogoprina. dimethicone, triethanolamine

# TopCare.

LONG LASTING

Oil-Free Moisturizer **Broad Spectrum** SPF15 Sunscreen

Long-Lasting Oil-Free Moisturizer Broad Spectrum SPF15 Sunscreen has been clinically proven to combine effective protection against the sun with long-lasting moisturization for skin that is softer, smoother and younger-looking.

#### All Day Moisturizing

This light, non-greasy lotion efficiently moisturizes skin for up to 12 hours. The pure formula is quickly absorbed, leaving skin softer and smoother.

### Efficient Protection Against the Sun

Broad spectrum SPF15 sunscreen assists in fighting premature aging caused by daily exposure to the sun.

#### Non-comedogenic (won 1 cloq pores)

The oil-free formulation is quickly absorbed so it won't clog pores leading to skin breakouts.

#### Long-Lasting Oil-Free Moisturizer Broad Spectrum SPF15 Sunscreen is:

Hypoallergenic Fragrance-Free

This product is not manufactured or distributed by

Neutrogena Corporation

· Alcohol-Free (no drying alcohol)

# Top Care.

LONG LASTING

# )il-Free Moisturizer

# **Broad Spectrum** SPF15 Sunscreen

for FACE

hypoallergenic non-comedogenic dermatologist tested

# TopCare.

LONG LASTING

Oil-Free Moisturizer **Broad Spectrum** SPF15 Sunscreen

#### Directions for Use

Use morning and evening, alone or under make-up. Apply over entire face and neck.

> Dermatologist Note: Humectants increase the water content in skin without causing shine, clogging pores or smearing make-up. Many oil-free products contain moisturizing agents with these humectants properties, making them ideal for oily skin.

# **SPF 15**

\*COMPARE TO NEUTROGENA® **OIL-FREE MOISTURE SPF 15 INGREDIENTS** 

with Broard Spectrum sun protection

4 FL OZ (118 mL)

OXYBENZONE

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



3 mL in 100 mL

**Carton Label** 

## LONG-LASTING OIL-FREE MOISTURIZER

OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)

avobenzone, octisalate, octocrylene and oxybenzone cream

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-360
--------------	----------------	--------------------	---------------

TOPICAL Route of Administration

#### Active Ingredient/Active Moiety **Ingredient Name Basis of Strength** Strength AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) AVOBENZONE 2 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** 4 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
C <b>ARBOMER 1342</b> (UNII: 809 Y72KV36)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIISOPROPYL ADIPATE (UNII: P7E6 YFV72X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZO LIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8 IX2SC1OH)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
TROLAMINE (UNII: 9O3K93S3TK)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:36800-360-45	1 in 1 CARTON			
1		118 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