SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN- homosalate, octisalate, and zinc oxide lotion

Obagi Cosmeceuticals 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.

SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN LOTION

Drug Facts

Active ingredients	Purpose
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Zinc Oxide 16.5%	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

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

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
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **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
- children under 6 months: Ask a doctor

Other information

- store at controlled room temperature: 15°–25°C (59°–77°F)
- protect this product from excessive heat and direct sun

Inactive ingredients

Water (Aqua), C15-19 Alkane, Octyldodecyl Neopentanoate, Polymethylsilsesquioxane, Sorbitan Olivate, Silica, Polyglyceryl-6 Polyrininoleate, Sodium Chloride, Xanthan Gum, Glycerin, Hydroxyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Disteardimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (candelilla) Wax, Beeswax, Dimethicone

Questions or comments?

1.800.636.7546

Monday–Friday 9 a.m.–4 p.m. Pacific Time Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

OBAGI[®]

MEDICAL

Sun Shield

MATTE

Broad

Spectrum

SPF 50

Sunscreen

Lotion

Non-Comedogenic

Dermatologist Tested

Net wt. 3 oz (85 g)

Sun Shield Matte Broad Spectrum SPF 50

This sunscreen provides broad spectrum protection against UVB and UVA radiation in an elegant, matte finish that is non-comedogenic, hypoallergenic and dermatologist tested. Sheer and fragrance free for all skin types.

Drug Facts

Active ingredients	Purpose
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
7inc Ovide 16 5%	Superroon

Uses

 helps prevent surbum
 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

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

- apply liberally 15 minutes before sun exposure use a water resistant sunscreen if swimming or
- use a water resistant sunscreen it swimming or sweating
 reapply at least every 2 hours
 Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease yether isk, 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

 children under 6 months: Ask a doctor

Other information

- store at controlled room temperature: 15°-25°C (59°-77°F)
- protect this product from excessive heat and direct sun

Inactive ingredients
Water (Aqua), C15-19 Akane, Octyldodecyl
Neopentanoate, Polymethylsilsasquioxane, Sorbitan
Olivate, Silica, Polyglyceryl-6 Polyrininoleate, Sodium
Chloride, Xarriban Gum, Glycerin, Hydrogyacetophenone, Disodium EDTA, 1,2-Hexanediol, Caprylyl Glycol, Sodium Hydroxide, Triethoxycaprylsilane, Polyhydroxystearic Acid, Disteardimonium Hectorite, Polyglyceryl-2 Isostearate, Euphorbia Cerifera (candelilla) Wax, Beeswax, Dimethicone

Questions or comments? 1.800.636.7546

Monday-Friday 9a.m.-4p.m. Pacific Time

Sun Shield



Broad Spectrum **SPF 50**



Sunscreen Lotion

Non-Comedogenic

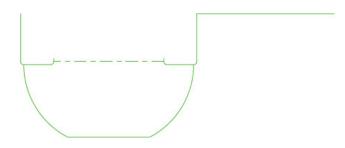
Dermatologist Tested

©2018 Obagi Cosmeceuticals LLC. All rights reserved. www.obagi.com

Made in USA with U.S. and Imported components 9499105 Net wt. 3 oz (85 g)

Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806 All product and brand names are trademarks of Obagi Cosmeceuticals LLC and/or its affiliates.





SUN SHIELD BROAD SPECTRUM SPF 50 MATTE SUNSCREEN

homosalate, octisalate, and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-140

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	165 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
Hydroxyacetophenone (UNII: G1L3HT4CMH)	
XANTHAN GUM (UNII: TTV12P4NEE)	
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Octyldodecyl Neopentanoate (UNII: X8725R883T)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
C15-19 Alkane (UNII: C187N1IM01)	
Disteardimonium Hectorite (UNII: X687XDK09L)	
POLYGLYCERYL-2 MONOISOSTEARATE (UNII: 7B8OE71MQC)	
Sorbitan Olivate (UNII: MDL271E3GR)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
1,2-HEXANEDIO L (UNII: TR0 46 Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
Candelilla Wax (UNII: WL0328HX19)	
Yellow Wax (UNII: 2ZA36H0S2V)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-140- 34	479 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/15/2019	
2	NDC:62032-140- 09	1 in 1 CARTON	07/15/2019	
2		85 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:62032-140- 05	28 g in 1 TUBE; Type 0: Not a Combination Product	07/15/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	07/15/2019	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment			
Name	Address	ID/FEI	Business Operations
Swiss American CDMO, LLC		080170933	MANUFACTURE(62032-140)

Revised: 9/2019 Obagi Cosmeceuticals LLC