

**OBAGI SUN SHIELD TINT WARM SUNSCREEN BROAD SPECTRUM SPF 50-
homosalate, octinoxate, titanium dioxide, 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.

**OBAGI®
Sun Shield TINT Warm Sunscreen
Broad Spectrum SPF 50**

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Homosalate 10%	Sunscreen
Octinoxate 7.5%	Sunscreen
Titanium dioxide 3.22%	Sunscreen
Zinc oxide 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
- **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
- 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°C–25°C (59°F–77°F)
- protect this product from excessive heat and direct sun

Inactive ingredients

Water, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Caprylyl Methicone, Polyglyceryl-10 Pentastearate, Butylene Glycol, Glyceryl Stearate, PEG-100 Stearate, Pentylene Glycol, Behenyl Alcohol, Physalis Angulata Extract, Dimethicone, PEG-40 Stearate, Phenoxyethanol, Lithothamnion Calcareum Powder, Glycerin, Mica, Sodium Stearoyl Lactylate, Polyhydroxystearic Acid, Mannitol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Citric Acid, Squalane, Xanthan Gum, Alumina, Stearic Acid, Diatomaceous Earth, Sodium Polyacrylate, Disodium EDTA, Ethylhexylglycerin, Synthetic Fluorophlogopite, Polysorbate 60, Zinc Sulfate, Sorbitan Oleate, Chlorphenesin, Tetrahexyldecyl Ascorbate, Tocopherol, Tin Oxide, Iron Oxides

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

Broad
Spectrum
SPF 50
Sunscreen
Lotion

WARM
TINT

Infrared
Defense

Non-comedogenic
Dermatologist tested

Net wt. 3 oz. (85 g)

**Sun Shield Tint
Broad Spectrum SPF 50**

This sunscreen combines UVA and UVB protection while helping to buffer the skin from the heat-derived oxidation process. Developed for warm skin tones, it is non-comedogenic, hypoallergenic and dermatologist tested. Sheer and fragrance free.

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Drug Facts (continued)

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Sun Shield

TINT
Broad Spectrum
SPF 50
Sunscreen
Lotion



WARM Infrared
Defense



The Skin Cancer Foundation recommends this product as an effective broad spectrum sunscreen

Non-comedogenic
Dermatologist tested

Net wt. 3 oz. (85 g)



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Long Beach, CA 90806

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OBAGI SUN SHIELD TINT WARM SUNSCREEN BROAD SPECTRUM SPF 50

homosalate, octinoxate, titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-160
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8.5 g in 85 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.375 g in 85 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.737 g in 85 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.25 g in 85 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
12-OXOOCTADECANOIC ACID (UNII: 31GL7GRO8F)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DOCOSANOL (UNII: 9G1OE216XY)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PHYSALIS ANGULATA WHOLE (UNII: W4TKW9D5GG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FUCUS VESICULOSUS (UNII: 535G2ABX9M)	
GLYCERIN (UNII: PDC6A3C0OX)	
MICA (UNII: V8A1AW0880)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
MANNITOL (UNII: 3OWL53L36A)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SQUALANE (UNII: GW89575KF9)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

STEARIC ACID (UNII: 4ELV7Z65AP)
XANTHAN GUM (UNII: TTV12P4NEE)
DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)
EDETATE DISODIUM (UNII: 7FLD91C86K)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
POLYSORBATE 60 (UNII: CAL22UVI4M)
ZINC SULFATE, UNSPECIFIED FORM (UNII: 89DS0H96TB)
CHLORPHENESIN (UNII: I670DAL4SZ)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
STANNIC OXIDE (UNII: KM7N50LOS6)
TOCOPHEROL (UNII: ROZB2556P8)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
FERROUS OXIDE (UNII: G7036X8B5H)
PHYMATOLITHON CALCAREUM (UNII: 6J1M3WA0ZK)
POLYGLYCERYL-10 PENTASTEARATE (UNII: PMX5872701)
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)
ZINC SULFATE MONOHYDRATE (UNII: PTX099XSF1)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-160-10	1 in 1 CARTON	12/01/2019	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/01/2019	

Labeler - Obagi Cosmeceuticals LLC (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American CDMO, LLC		080170933	MANUFACTURE(62032-160)