

ROSACLEAR SKIN BALANCING SUN PROTECTION SPF 30 SUNCREEN- titanium dioxide and zinc oxide lotion

OMP, 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.

ROSACLEAR® SKIN BALANCING SUN PROTECTION SPF 30 SUNSCREEN LOTION

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Titanium Dioxide 2.0%	Sunscreen
Zinc Oxide 15.5%	Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection.

Warnings

For external use only.

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash or irritation develops and lasts.

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

Directions

- apply liberally before sun exposure and as needed.
- children under 6 months of age: ask a doctor.
- reapply as needed or after towel drying, swimming, or sweating.

Other information

- store at controlled room temperature: 15-25°C (59-77°F).
- Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer and other harmful effects of the sun.

Inactive ingredients

Alumina, Butylparaben, Cetearyl Alcohol, Coco-Glucoside, C12-15 Alkyl Benzoate, Dipropylene Glycol, PEG-6, Ethylparaben, Glycerin, Hydroxyethyl Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer, Iron Oxides, Isobutylparaben, Isohexadecane, Isopropyl Titanium Triisostearate/Triethoxycaprylylsilane Crosspolymer, Methylparaben, Mica, Phenoxyethanol, Polyhydroxystearic Acid, Propylparaben, Tocopheryl Acetate, Triethoxycaprylylsilane, Water.

Dist. by OMP, Inc.
3760 Kilroy Airport Way Suite 500
Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - 88 mL Bottle Label

OBAGI®
MEDICAL

rosaclear®
system

· NON-COMEDOGENIC · NON-COMEDOGENIC

SKIN BALANCING
SUN PROTECTION
SPF 30
SUNSCREEN LOTION
3 FL.OZ. (88 mL)

Skin Balancing Sun Protection SPF 30 contains reflective agents that help reduce the appearance of redness and blotchiness.



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High Sun Protection Product
Dist. by OMP, Inc.
3760 Kilroy Airport Way Suite 500
Long Beach, CA 90806
www.obagi.com Made in U.S.A.
7264 10726413Y



rosaclear[®]
system



**SKIN BALANCING
SUN PROTECTION**
SPF 30
SUNSCREEN LOTION



3 FLOZ. (88 mL)

ROSACLEAR SKIN BALANCING SUN PROTECTION SPF 30 SUNCREEN

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	20 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	155 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0KO0R)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCO GLUCOSIDE (UNII: ICS790225B)	
METHYLPARABEN (UNII: A218C7HI9T)	
ALUMINUM OXIDE (UNII: LM26O6933)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ISOHEXADECANE (UNII: 918X10UF1E)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERIN (UNII: PDC6A3C0OX)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	GRAY	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-103-90	88 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/01/2009	

Labeler - OMP, Inc. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American Products		611921669	MANUFACTURE(62032-103)

Revised: 12/2011

OMP, Inc.