CONDITION AND ENHANCE HEALTHY SKIN PROTECTION SPF 35- octinoxate and zinc oxide cream
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.

CONDITION & ENHANCE
HEALTHY SKIN
PROTECTION
SPF 35

Drug Facts

Active Ingredients

Octinoxate, 7.5%, Zinc Oxide, 9%

Purpose

Sunscreens

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 physician if

- Rash or irritation develops and lasts.

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

Directions

- Apply generously and evenly 15 minutes before sun exposure.
- Children under six months of age: Ask a physician.
- Reapply as needed or after towel drying, swimming or perspiring.

Other Information

- Store at controlled room temperature: 15°-30°C (59°-86°F).
- High sun protection product.
- 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

Butylparaben, cetearyl alcohol, citric acid, C13-14 isoparaffin, diethanolamine cetyl phosphate, disodium edetate, ethylparaben, isobutylparaben, isopropyl palmitate, laureth-7, methylparaben, octyl stearate, phenoxyethanol, polyacrylamide, polyether-1, polysorbate 60, propylparaben, purified water, sodium hydroxide, triethoxycaprylysilane.

Dist. by OMP Inc. Long Beach, CA 90802

PRINCIPAL DISPLAY PANEL - 90 mL Bottle Label

OBAGI®
MEDICAL

CONDITION & ENHANCE

AM 6

healthy skin
protection
SPF 35

Broad-Spectrum
UVA/UVB Sunscreen

RECOMMENDED
SKIN
CANCER
FOUNDATION

3 FL. OZ. (90 mL)

CONDITION AND ENHANCE HEALTHY SKIN PROTECTION SPF 35

octinoxate and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62032-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	90 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	

WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
LAURETH-7 (UNII: Z95S6G8201)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-119-10	30 mL in 1 BOTTLE, PLASTIC		
2	NDC:62032-119-90	90 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/01/2002	

Labeler - OMP, Inc. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
Swiss-American Products		611921669	MANUFACTURE(62032-119)

Revised: 12/2011 OMP, Inc.