

**PRIME PROMETICS LIPOIL SPF 35 WARM SIENNA- zinc oxide oil
COSMAX USA, CORP**

PRIME Prometics Lip Oil SPF 35 Warm Sienna

Active Ingredients

Zinc Oxide 13.5%

Purpose

Sunscreen

USES

Uses

- Helps prevent sunburn
- I 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 doctor if rash occurs

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

DIRECTIONS

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- Apply generously and evenly 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use water resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of certain cancer and early aging. To decrease this risk, regularly use a sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
- Limit in the sun, especially from 10 a.m. - 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months:

Ask doctor.

OTHER INFORMATION

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Protect Product in this container from excessive heat and direct sun

INACTIVE INGREDIENTS:

Diisostearyl Malate, Polybutene, Hydrogenated Polyisobutene, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Microcrystalline Wax, Silica Dimethyl Silylate, Bis-Diglyceryl Polyacyladipate-2, Sorbitan Olivatate, Isononyl Isononanoate, Sorbitan Isostearate, Isostearic Acid, Lecithin, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, VP/Hexadecene Copolymer, Iron Oxides (CI 77491), Titanium Dioxide (CI 77891), Iron Oxides (CI 77492), Flavor, Menthone Glycerin Acetal, Iron Oxides (CI 77499), Dehydroacetic Acid, Red 7 Lake (CI 15850), Rosa Canina Seed Oil, Mangifera Indica (Mango) Seed Butter, Ricinus Communis (Castor) Seed Oil, Hyaluronic Acid, Hydrogenated Castor Oil, and Tocopherol.



PRIME PROMETICS LIPOIL SPF 35 WARM SIENNA

zinc oxide oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68577-225
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13.5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
CI 77491 (UNII: 1K09F3G675)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
MANGIFERA INDICA (MANGO) SEED BUTTER (UNII: 4OXD9M35X2)	
HYALURONIC ACID (UNII: S270N0TRQY)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
VP/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
CI 77499 (UNII: XM0M87F357)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
ROSA CANINA SEED OIL (UNII: MHT97MG5P8)	
HYDROGENATED POLYISOBUTENE (450 MW) (UNII: 7YR4ZFS62E)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
RICINUS COMMUNIS (CASTOR) SEED OIL (UNII: D5340Y2I9G)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
TOCOPHEROL (UNII: ROZB2556P8)	
MENTHONE GLYCERIN ACETAL (UNII: 7QQ1EE6RCP)	
CI 77492 (UNII: EX438O2MRT)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CI 15850 (UNII: 481744AI4O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68577-225-01	1 in 1 CARTON	10/01/2025	
1		10 mL 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 Drug	M020	10/01/2025	

Labeler - COSMAX USA, CORP (010990210)

Registrant - COSMAX USA, CORP (010990210)

Establishment

Name	Address	ID/FEI	Business Operations
COSMAX USA, CORP		010990210	manufacture(68577-225)

Revised: 12/2025

COSMAX USA, CORP