

OS-01 LIP SPF BS SPF15- zinc oxide cream
ONESKIN INC.

Drug Facts

Active ingredie:
Zinc Oxide 5.5%.

Purpose: 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.
- Reapply at least every 2 hours
- Use a water-resistant sunscreen If swimming or sweating.
- Children under 8 months of age: Ask a Doctor.
- Sun Probation 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

Other information

Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients

Simmondsia Chinensis (Jojoba) Seed Oil, Ethylene/Propylene/Styrene Copolymer, Ethylhexyl Palmitate, Butyl octyl Salicylate. Caprylic/Capric Triglyceride, Water (Aqua), Garcinia

Indica Seed Butter, Tocopheryl Acetate, Butylene/Ethylene/Styrene Copolymer, Glyceryl Oleate, Glyceryl Dioleate, Glycerin, Oleic Acid, Tribehenin, Sorbitan Isostearate, Palmitoyl Tripeptide-1, Dipalmitoyl Hydroxyproline, Trihydroxystearin, Sodium Hyaluronate, Glucomannan, Tetrahexyldecyl Ascorbate, Bisabolol, Decapeptide-52*, Ethylhexylglycerin, Caprylyl/Capryl Glucoside, Propanediol, Ectoin, Centella Asiatica Extract, Hippophae Rhamnoides oil, Helianthus Annuus (Sunflower) Seed Oil, Copernicia Cerifera (Carnauba)Wax, Tocopherol, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Polyhydroxy stearic Acid, Polyglyceryl-3 Polyricinoleate, Isostearic Acid, Lecithin, Beta-Sitosterol, Squalene, Lactic Acid, Palmitic acid.



OS-01 LIP SPF BS SPF15

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84451-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
OLEIC ACID (UNII: 2UMI9U37CP)	
BISABOLOL (UNII: 24WE03BX2T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE (UNII: AUG1H506LY)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL (UNII: 3W1JG795YI)	
SODIUM HYALURONATE (UNII: YSE9PPT4TH)	
GLYCERYL DIOLEATE (UNII: Z3MP1W91CW)	
ECTOIN (UNII: 7GXZ3858RY)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL (UNII: 724GKU717M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)	
WATER (UNII: 059QF0KO0R)	
GARCINIA INDICA SEED BUTTER (UNII: US2H3D7800)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
SQUALENE (UNII: 7QVM220FJH)	
LACTIC ACID (UNII: 33X04XA5AT)	
GLUCOMANNAN (UNII: 36W3E5TAMG)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
ETHYLENE (UNII: 91GW059KN7)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
HIPPOPHAE RHAMNOIDES SEED OIL (UNII: T53SBG6741)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
1-BUTENE (UNII: LY001N554L)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
CAPRYLYL/CAPRYL GLUCOSIDE (UNII: E00JL9G9K0)	
PROPANEDIOL (UNII: 5965N8W85T)	
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TOCOPHEROL (UNII: ROZB2556P8)	
PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE (UNII: 255PIF62MS)	
BETA-SITOSTEROL (UNII: S347WMO6M4)	
PALMITIC ACID (UNII: 2V16EO95H1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84451-004-02	1 in 1 CARTON	05/07/2025	
2	NDC:84451-004-	12 q in 1 TUBE; Type 0: Not a Combination		

01	Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/07/2025	

Labeler - ONESKIN INC. (088037418)

Revised: 5/2025

ONESKIN INC.