

OS-01 FACE SPF BD SPF 30 TINTED MEDIUM/DEEP- zinc oxide cream
ONESKIN INC.

Drug Facts

Active ingredient: Zinc Oxide 17.5 %.

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 6 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

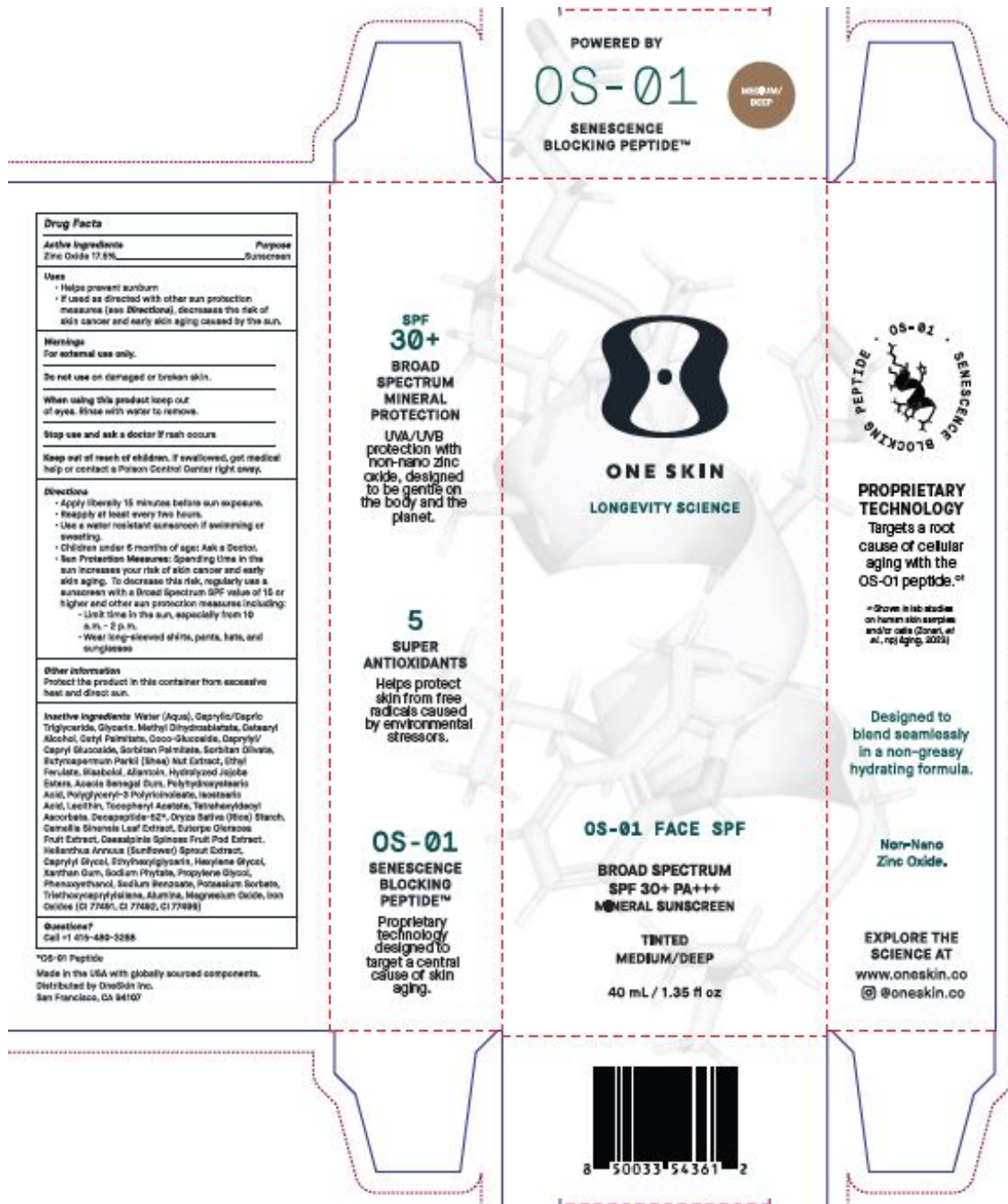
Other information

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

Inactive Ingredients

Water (Aqua),Caprylic/Capric Triglyceride, Glycerin, Methyl Dihydroabietate, Cetearyl Alcohol, Cetyl Palmitate, Coco-Glucoside, Caprylyl/Capryl Glucoside, Sorbitan Palmitate, Sorbitan Oliviate, Butyrospermum Parkii (Shea) Nut Extract, Ethyl Ferulate, Bisabolol, Allantoin, Hydrolyzed Jojoba Esters, Acacia Senegal Gum, Polyhydroxystearic acid, Polyglyceryl-3 Polyricinoleate, Isostearic acid, Lecithin, Tocopheryl Acetate, Tetrahexyldecyl Ascorbate, Decapeptide-52*,Oryza Sativa (Rice) Starch, Camellia

Sinensis Leaf Extract, Euterpe Oleracea Fruit Extract, Caesalpinia Spinosa Fruit Pod Extract, Helianthus Annuus (Sunflower) Sprout Extract, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Xanthan Gum, Sodium Phytate, Propylene Glycol, Phenoxyethanol, Sodium Benzoate, Potassium Sorbate, Triethoxycaprylylsilane, Alumina, Magnesium Oxide, Iron Oxides (CI 77491, CI 77492, CI 77499)



OS-01 FACE SPF BD SPF 30 TINTED MEDIUM/DEEP

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84451-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.5 g in 100 g
Inactive Ingredients		
Ingredient Name	Strength	
HYDROLYZED JOJOBA ESTERS (UNII: UDR641JW8W)		
ACACIA SENEGAL GUM (UNII: 5C5403N26O)		
SODIUM PHYTATE (UNII: 88496G1ERL)		
CETEARYL ALCOHOL (UNII: 2DMT128M1S)		
ALLANTOIN (UNII: 344S277G0Z)		
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)		
CI 77491 (UNII: 1K09F3G675)		
ISOSTEARIC ACID (UNII: X33R8U0062)		
CAESALPINIA SPINOSA FRUIT POD (UNII: EXY4496LWD)		
HEXYLENE GLYCOL (UNII: KEH0A3F75J)		
XANTHAN GUM (UNII: TTV12P4NEE)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CI 77499 (UNII: XM0M87F357)		
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
ACAI (UNII: 46AM2VJ0AW)		
SORBITAN OLIVATE (UNII: MDL271E3GR)		
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)		
CAPRYLYL/CAPRYL GLUCOSIDE (UNII: E00JL9G9K0)		
SORBITAN PALMITATE (UNII: 77K6Z421KU)		
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
CI 77492 (UNII: EX438O2MRT)		
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)		
CETYL PALMITATE (UNII: 5ZA2S6B08X)		
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)		
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
ORYZA SATIVA (RICE) STARCH (UNII: 4DGK8B7I3S)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
ETHYL FERULATE (UNII: 5B8915UELW)		
BISABOLOL (UNII: 24WE03BX2T)		
ALUMINA (UNII: LMI26O6933)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)		
COCO-GLUCOSIDE (UNII: ICS790225B)		
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)		
CAMELLIA SINENSIS LEAF (UNII: W2ZU1RY8B0)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
SHEANUT (UNII: 84H6HBP32L)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84451-006-02	1 in 1 CARTON	05/12/2025	
1	NDC:84451-006-01	40 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 Drug	M020	05/12/2025	

Labeler - ONESKIN INC. (088037418)

Revised: 5/2025

ONESKIN INC.