

**OS-01 FACE SPF BS SPF30 TINTED- zinc oxide cream  
ONESKIN INC.**

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**Drug Facts**

Active ingredients - Zinc Oxide 17.5 %

Purpose - Sunscreen

Uses -

Helps prevent sunburn

If used as directed with other sun protection measures (See direction), decreases the risk of skin cancer and early skin aging caused by the sun.

Warning - For external use only

Do not use on damaged or broken skin

When using this product keep out of eye. Rinse with water to remove.

Stop use and ask doctor if rash occurs

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Direction-

Apply liberally 15 minutes before sun exposure.

Reapply at least every two hours.

Use a water-resistant sunscreen if swimming or sweating.

Children under 6 months of age: Ask a doctor.

Sun protection measures: spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a broad-spectrum value of 15 or higher and other sun protection measures including:

Limit time in the sun. especially from 10 am to 2 pm

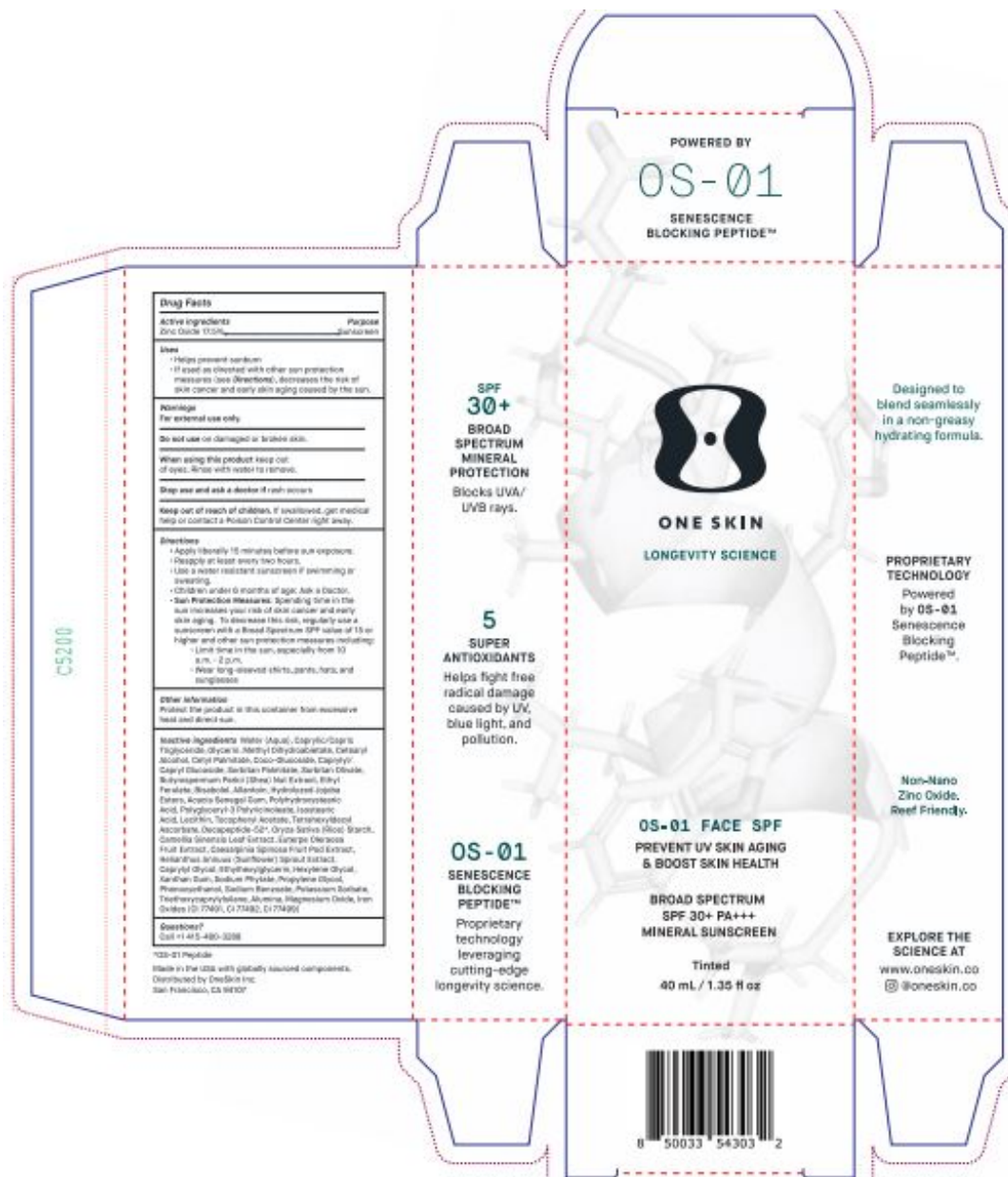
Wear long-sleeved shirts, pants hats and sunglasses.

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 Olivatate, 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, CI77499)



## OS-01 FACE SPF BS SPF30 TINTED

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84451-002
<b>Route of Administration</b>	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

<b>PEPTIDE-T</b> (UNII: 05DYM3ZS1X)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)
<b>STARCH, RICE</b> (UNII: 4DGK8B7I3S)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)
<b>ETHYL FERULATE</b> (UNII: 5B8915UELW)
<b>HELIANTHUS ANNUUS SPROUT</b> (UNII: 4P26HG1S5W)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>HYDROLYZED JOJOBA ESTERS (POTASSIUM SALTS)</b> (UNII: CH428W5O62)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)
<b>SORBITAN MONOPALMITATE</b> (UNII: 77K6Z421KU)
<b>SHEANUT</b> (UNII: 84H6HBP32L)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)
<b>ACAI</b> (UNII: 46AM2VJ0AW)
<b>CAESALPINIA SPINOSA FRUIT POD</b> (UNII: EXY4496LWD)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)
<b>PHYTATE SODIUM</b> (UNII: 88496G1ERL)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>ACACIA</b> (UNII: 5C5403N26O)
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>METHYL DIHYDROABIETATE</b> (UNII: 7666FJ0J9F)
<b>CAPRYLYL/CAPRYL OLIGOGLUCOSIDE</b> (UNII: E00JL9G9K0)
<b>ALLANTOIN</b> (UNII: 344S277G0Z)
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84451-002-02	1 in 1 CARTON	09/13/2023	

<b>1</b>	NDC:84451-002-01	40 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
	<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	OTC Monograph Drug	M020	09/13/2023	

**Labeler -** ONESKIN INC. (088037418)

Revised: 9/2024

ONESKIN INC.