

OS-01 BODY SPF 30- zinc oxide cream
ONESKIN, INC

Drug Facts

Active ingredients - Zinc Oxide 14 %

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 after 80 minutes of swimming or sweating.

immediately after towel drying, at least every 2 hours

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.

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

Inactive Ingredients: Caprylic/Capric Triglyceride 40 - 65 Butyloctyl Salicylate, C13-15 Alkane, Stearalkonium Hectorite, Coconut Alkanes, Euphorbia Cerifera (Candelilla) Wax, Helianthus Annuus (Sunflower) Seed Wax, Propylene Carbonate, Quaternium-90 Bentonite, Butyrospermum Parkii Nut Extract, Decapeptide-52, Camellia Oleifera (Tea) Seed Oil, Caesalpinia Spinosa Fruit Pod Extract, Helianthus Annuus (Sunflower) Sprout Extract, Aloe Barbadensis Leaf Extract, Carthamus Tinctorius Seed Oil, Lactobacillus/Acerola Cherry Ferment, Coco-Caprylate/Caprinate, Ceramide NP, Ceramide AP, Ceramide EOP, Ethylhexylglycerin, Caprylyl Glycol, Hexylene Glycol, Polyhydroxystearic acid, Polyglyceryl-3 Polyricinoleate, Isostearic acid, Lecithin, Phytosphingosine, Cholesterol, Sodium lauroyl lactylate, Carbomer, Xanthan gum, Water, Propylene Glycol, Triethyl Citrate, Citric Acid, Sodium Benzoate, Phenoxyethanol.

<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> <tr> <td>Zinc Oxide 10%</td> <td>Sunscreen</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> 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. <p>Warnings For external use only.</p> <p>Do not use on damaged or broken skin.</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure. Reapply: <ul style="list-style-type: none"> after 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours 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 this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats, and sunglasses <p>Other information Protect the product in this container from excessive heat and direct sun.</p> <p>Inactive ingredients: Caprylic/Capric Triglyceride, Butyloctyl Salicylate, C12-15 Alkane, Shearwater Hectrite, Coconut Alkanes, Euphorbia Cerifera (Candelilla) Wax, Helianthus Annuus (Sunflower) Seed Wax, Polyethylene Carbonate, Guatemalan-90 Benzoin, Butyrospermum Parkii Nut Extract, Decapeptide-02*, Camellia Oleifera (Tea) Seed Oil, Castalja Spicosa Fruit Pod Extract, Helianthus Annuus (Sunflower) Sprout Extract, Aloe Barbadensis Leaf Extract, Carthamus Tinctorius Seed Oil, Lactobacillus Ferment Cherry Ferment, C12-C14 Caprylate/Caprate, Octamide HP, Ceraflax AP, Ceraflax 608, Ethylhexylglycerin, Caprylyl Glycol, Hexylene Glycol, Polyhydroxybutyric acid, Polyglyceryl-3 Polyricinoleate, Isosorbate acid, Lecithin, Phytosphingosine, Cholesterol, Sodium Lauryl Sulfate, Carbomer, Sorbitol gum, Water, Propylene Glycol, Yarrow Oilate, Citric Acid, Sodium Benzoate, and Phenylethanol</p> <p>Questions? Call +1 415-480-2388</p> <p><small>*US-01 Peptide Made in the USA with globally sourced components. Distributed by OneSkin Inc. San Francisco, CA 94107</small></p>	Active Ingredients	Purpose	Zinc Oxide 10%	Sunscreen	<p style="text-align: center;">SPF 30+ BROAD SPECTRUM MINERAL PROTECTION</p> <p style="text-align: center;">UVA/UVB protection with non-nano zinc oxide, shown to be the safest for the body and the planet.</p> <p style="text-align: center;">5 SUPER ANTIOXIDANTS</p> <p style="text-align: center;">Helps neutralize free radicals due to UV, blue light, IR, and pollution.</p> <p style="text-align: center;">OS-01 SENESCENCE BLOCKING PEPTIDE*</p> <p style="text-align: center;">Proprietary technology designed to target a central cause of skin aging.</p>	<div style="text-align: center;">  <p>ONE SKIN LONGEVITY SCIENCE</p> </div> <p style="text-align: center;">OS-01 BODY SPF PREVENT UV SKIN AGING & BOOST SKIN HEALTH</p> <p style="text-align: center;">BROAD SPECTRUM SPF 30+ PA+++</p> <div style="border: 1px solid black; border-radius: 15px; padding: 5px; text-align: center; width: fit-content; margin: 0 auto;"> WATER RESISTANT (80 MINUTES) </div> <p style="text-align: center;">Mineral Sunscreen</p> <p style="text-align: center;">100 mL / 3.4 fl oz</p>	<p style="text-align: center;">REEF-FRIENDLY FORMULA</p> <p style="text-align: center;">Non-nano mineral protection and cutting-edge longevity science delivered in a lightweight, moisturizing, reef-friendly formula.</p> <p style="text-align: center;">EXPLORE THE SCIENCE AT www.oneskin.co @oneskin.co</p>
Active Ingredients	Purpose						
Zinc Oxide 10%	Sunscreen						

OS-01 BODY SPF 30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84451-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BIFIDOBACTERIUM ANIMALIS LACTIS (UNII: 5307V7XW8I)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
SHEANUT (UNII: 84H6HBP32L)	

PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)
SODIUM BENZOATE (UNII: OJ245FE5EU)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
CAESALPINIA SPINOSA FRUIT POD (UNII: EXY4496LWD)
SAFFLOWER OIL (UNII: 65UEH262IS)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)
HELIANTHUS ANNUUS SPROUT (UNII: 4P26HG1S5W)
ISOSTEARIC ACID (UNII: X33R8U0062)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
STEARALKONIUM HECTORITE (UNII: OLV698AH5P)
QUATERNIUM-90 BENTONITE (UNII: 97K5YEF88C)
CAMELLIA OIL (UNII: T1PE06G0VE)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
MALPIGHIA EMARGINATA SEED (UNII: 1X7L93686M)
CERAMIDE NP (UNII: 4370DF050B)
CERAMIDE AP (UNII: F1X8L2B00J)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CHOLESTEROL (UNII: 97C5T2UQ7J)
XANTHAN GUM (UNII: TTV12P4NEE)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
C13-15 ALKANE (UNII: 114P5I43UJ)
COCONUT ALKANES (UNII: 1E5KJY107T)
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84451-001-02	1 in 1 CARTON	06/20/2024	
1	NDC:84451-001-01	100 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	06/20/2024	

