

INVISIBLE PHYSICAL DEFENSE SPF 30- zinc oxide lotion

Dermologica, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Invisible Physical Defense SPF 30

Drug Facts

Active ingredient

Zinc Oxide (20%)

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see Directions), helps decrease 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 30 minutes before sun exposure.
- Reapply at least every two hours.
- Use a water resistant sunscreen if swimming or sweating.
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To help decrease this risk, regularly use a sunscreen with a broad spectrum SPF 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-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months: ask a doctor.

Other information

- Protect this product from excessive heat and direct sun.

Inactive ingredients

Water/Aqua/Eau, Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Dimethicone, Butyloctyl Salicylate, Butylene Glycol, Glycerin, Silica, Polyhydroxystearic Acid, PEG-10 Dimethicone, Argania Spinosa Kernel Oil, Cordyceps Sinensis Extract, Trametes Versicolor Extract, Sodium Hyaluronate, Camellia Sinensis Leaf Extract, Eucalyptus Globulus Leaf Oil, Lavandula Spica (Lavender) Flower Oil, Tocopheryl Acetate, Sodium Chloride, Stearalkonium Hectorite, Pentylene Glycol, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Propanediol, Dimethicone Crosspolymer, Sodium Citrate, Propylene Carbonate, Xanthan Gum, Caprylyl Glycol, Bisabolol, Lavandula Hybrid Oil, Ethylhexylglycerin, Sodium Hydroxide, Potassium Sorbate, Sodium Benzoate.

Questions or comments

Call toll free 1-800-831-5150 in the US.

PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton

invisible

physical

defense

dermalogica

SPF

30

broad spectrum

weightless

physical

sunscreen

1.7 US FL OZ / 50 mL e

invisible
physical
defense
spf 30

invisible
physical
defense

SPF
30
FPS

broad spectrum
large spectre

malogica

Drug Facts (continued)

Other information

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weightless
physical
sunscreen
écran solaire
physique léger

derm

1.7 US FL OZ / 50 mL e



MIX
Paper from
responsible sources
FSC®

invisible physical
defense spf 30

Invisible, weightless defense that blends easily on skin, featuring only non-nano Zinc Oxide. Say goodbye to thick, white residue with this

Drug Facts

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Purpose Sunscreen

Uses

day goodbye to thick, white residue with a physical SPF formula that provides added blue light protection and helps soothe away the effects of environmental aggressors. Bioactive Mushroom Complex helps soothe skin and reduce UV-induced redness and dryness. Antioxidant Green Tea helps defend skin against free radical damage. Ideal for all skin types, including sensitive.

Un écran solaire léger et invisible à base d'oxyde de zinc sans nanoparticules qui se fond dans la peau. Dites adieu aux résidus blancs grâce à cette formule avec FPS physique qui offre une protection accrue contre la lumière bleue et aide à contrer les effets des agressions environnementales. Un complexe de champignons bioactifs aide à apaiser la peau et à réduire les rougeurs et la sécheresse causées par les rayons UV. Le thé vert antioxydant aide à protéger la peau des dommages causés par les radicaux libres. Idéal pour tous les types de peaux, y compris les peaux sensibles.

 **dermalogica.info**

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INVISIBLE PHYSICAL DEFENSE SPF 30

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-909
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
Dimethicone (UNII: 92RU3N3Y1O)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Glycerin (UNII: PDC6A3C0OX)	
Butylene Glycol (UNII: 3XUS85K0RA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYHYDROXYSTEARIC ACID STEARATE (UNII: 8KQ7I65XZE)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	

ARGAN OIL (UNII: 4V59G5UW9X)
OPHIOCORDYCEPS SINENSIS (UNII: 8Q1GYP08KU)
TRAMETES VERSICOLOR FRUITING BODY (UNII: 4C900477MT)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
EUCALYPTUS OIL (UNII: 2R04ONI662)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
LAVENDER OIL (UNII: ZBP1YXW0H8)
Sodium Chloride (UNII: 451W47IQ8X)
Stearalkonium Hectorite (UNII: O LX698AH5P)
Pentylene Glycol (UNII: 50C1307PZG)
Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone (UNII: 25G622K2RA)
Propanediol (UNII: 5965N8W85T)
DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
Propylene Carbonate (UNII: 8D08K3S51E)
Xanthan Gum (UNII: TTV12P4NEE)
Caprylyl Glycol (UNII: 00YIU5438U)
LEVOMENOL (UNII: 24WE03BX2T)
Ethylhexylglycerin (UNII: 147D247K3P)
LAVANDIN OIL (UNII: 9RES347CKG)
Sodium Hydroxide (UNII: 55X04QC32I)
Potassium Sorbate (UNII: 1VPU26JZZ4)
Sodium Benzoate (UNII: OJ245FE5EU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-909-01	1 in 1 CARTON	03/05/2020	
1		7 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-909-02	50 mL in 1 TUBE; Type 0: Not a Combination Product	03/05/2020	
3	NDC:68479-909-04	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/05/2020	
4	NDC:68479-909-00	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/05/2020	

Labeler - Dermalogica, Inc. (177698560)

Establishment

Name	Address	ID/FEI	Business Operations
McKenna		090631412	MANUFACTURE(68479-909)