

**PURELY PHYSICAL SPF 47- zinc oxide, titanium dioxide cream**  
**Private Label Skin Care**

*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.*

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**Purely Physical SPF 47**

***Drug Facts***

***Active Ingredients***

Zinc Oxide 10%

Titanium Dioxide 5.5%

***Purpose***

Sunscreen

***Use*** Helps prevent sunburn • If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

***Warnings*** For external use only.

***When using this product*** • keep out of eyes. Rinse with water to remove. Stop use and ask physician if rash occurs.

***Keep out of reach of children.*** If swallowed, get medical help or contact a Poison Control Center right away.

***Directions*** • Apply on a clean, dry face in the morning avoiding delicate eye area. Apply 15 minutes before sun exposure. May be used daily. Consult physician before use. Reapply after prolonged exposure, physical activity, perspiration or contact with water.

***Precautions*** • 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 value of SPF 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. Children under 6 months of age: Ask a physician.

***Inactive Ingredients:*** Water/Aqua/Eau, Caprylyl Methicone, C12-15 Alkyl Benzoate, Cyclopentasiloxane, Lauryl PEG-9 Polydimethylsiloxylethyl Dimethicone, Glycerin, Alumina, Sodium Chloride, Methicone, Dimethicone, Polyglyceryl-3 Polydimethylsiloxylethyl Dimethicone, Triethoxysilylethyl Polydimethylsiloxylethyl Hexyl Dimethicone, 1,2-

Hexanediol, Caprylyl Glycol, Dimethicone/PEG-10/15 Crosspolymer, Disteardimonium Hectorite, Polyhydroxystearic Acid, Propylene Carbonate, Disodium EDTA, Ethylhexylglycerin, Triethoxycaprylylsilane, Phenoxyethanol

brandMD®

SKIN CARE

**SUN DEFENSE**

**medical grade**

✓ Broad-spectrum coverage against UVA and UVB

✓ Chemical-free active ingredients

✓ Water resistant (80 minutes)

**RECOMMENDED SKIN TYPES**

A - ACNE

C - COMBO

D - DRY

N - NORMAL

O - OILY

S- SENSITIVE

brandMD®

Chatsworth, CA 91311

[www.brandMD.com](http://www.brandMD.com)

Toll Free: (877) 252-7546

**Packaging**



# Purely Physical SPF 47

**SUN DEFENSE**  
medical grade

- Broad-spectrum coverage against UVA and UVB
- Chemical-free active ingredients
- Water resistant (80 minutes)

4.9 oz | 139 g

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RECOMMENDED SKIN TYPES

<b>A</b> ACNE	<b>C</b> COMBO	<b>D</b> DRY	<b>N</b> NORMAL	<b>O</b> OILY	<b>S</b> SENSITIVE
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## PURELY PHYSICAL SPF 47

zinc oxide, titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC: 72957-005(NDC:39765-020)
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 g in 100 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5.5 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>METHICONE (20 CST)</b> (UNII: 6777U11MKT)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S)</b> (UNII: RLA2U05Z4Q)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>DIMETHICONE/PEG-10/15 CROSSPOLYMER</b> (UNII: 21AS8B1BSS)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72957-005-01	139 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2020	

**Labeler** - Private Label Skin Care (116996962)

## Establishment

Name	Address	ID/FEI	Business Operations
Private Label Skin Care		116996962	relabel(72957-005)