# SUPER BB BEAUTY BALM POWDER SPF 30- titanium dioxide, zinc oxide powder PHYSICIANS FORMULA 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.

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#### **Super BB Beauty Balm Powder**

## **Active ingredients**

Titanium Dioxide 15%
Zinc Oxide 10%

#### **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

use a water resistant sunscreen if swimming or sweating

reapply at least every 2 hours

children under 6 months: 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 preotection 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**

Mica, Zinc Stearate, Octyldodecyl Stearoyl Stearate, Dimethicone, Calcium Aluminum Borosilicate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Lauroyl Lysine, Boron Nitride, Triethylhexanoin, Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, o-Cymen-5-ol, Silica, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Salix Alba (Willow) Bark Extract, Glycerin, Water/Eau, Lysolecithin, Perilla Ocymoides Seed Oil, Synthetic Fluorphlogopite, Tin Oxide, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891).

#### Questions or comments?

Call toll free 1-800-227-0333

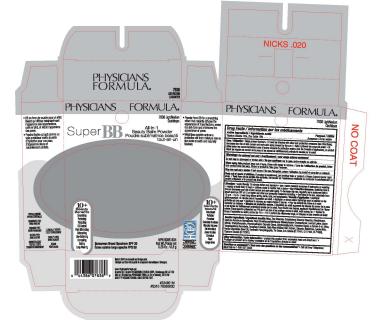
## **Principle Display Panel**











## **SUPER BB BEAUTY BALM POWDER SPF 30**

titanium dioxide, zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31645-209
Route of Administration	TOPICAL		

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

Inactive Ingredients		
Ingredient Name	Strength	
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
MICA (UNII: V8A1AW0880)		
ZINC STEARATE (UNII: H92E6QA4FV)		
OCTYLDODECYL STEAROYL STEARATE (UNII: 3D47Q6D93C)		
LAUROYL LYSINE (UNII: 113171Q70B)		
DIMETHICONE (UNII: 92RU3N3Y1O)		

HEXYLENE GLYCOL (UNII: KEH0A3F75J)  TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)  SALIX ALBA BARK (UNII: 205MXS71H7)  GLYCERIN (UNII: PDC6A3C0OX)  TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)  .ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)  CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
SALIX ALBA BARK (UNII: 205MXS71H7)  GLYCERIN (UNII: PDC6A3C0OX)  TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)  .ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
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.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)
O-CYMEN-5-OL (UNII: H41B6Q1I9L)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX43802MRT)
FERROSOFERRIC OXIDE (UNII: XM0M87F357)
LYSOPHOSPHATIDYLCHOLINE, SOYBEAN (UNII: CQD833204Z)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
PERILLA FRUTESCENS SEED OIL (UNII: 322MS57V7Z)
WATER (UNII: 059QF0KO0R)
STANNIC OXIDE (UNII: KM7N50LOS6)

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:31645-209- 02	1 in 1 CARTON	12/27/2012		
1	NDC:31645-209- 01	8.3 g in 1 PACKAGE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/27/2012	

## Labeler - PHYSICIANS FORMULA INC (021261805)

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