# INVINCIBLE SETTING POWDER SPF 45- titanium dioxide, zinc oxide powder TAYLOR JAMES, LTD.

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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#### **Invincible Setting Powder SPF 45**

Active ingredients Purpose

Titanium Dioxide 15.7% Sunscreen

Zinc Oxide 20% Sunscreen

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

Keep out of reach of children

Stop use and ask a doctor if rash occurs

**Warnings** For external use only

Do not on damaged or broken skin

When using this product keep out of eyes

Rinse with water to remove

If swallowed, get medical help or contact a Poison Center right away

**Directions** [Apply liberally and evenly to face before sun exposure

Reapply after 40 minutes of swimming or sweating

immediately after towel drying

at least every 2 hours

Children under 6 months: Ask a doctor

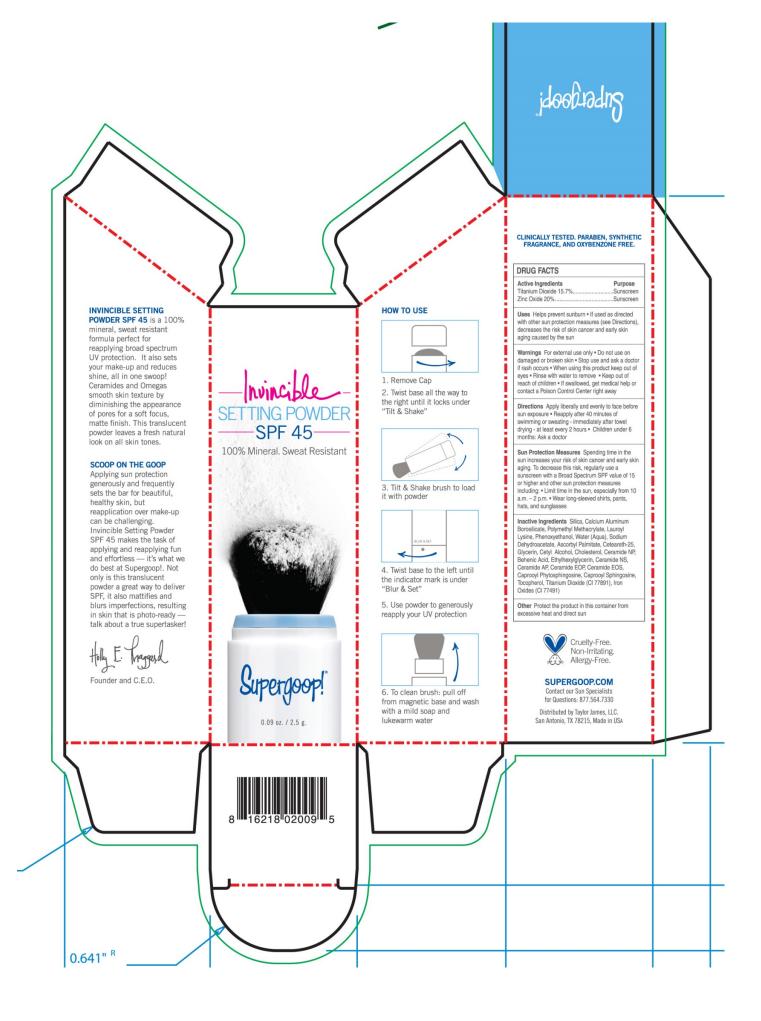
**Inactive Ingredients** [Silica, Calcium Aluminum Borosilicate, Polymethyl Methacrylate, Lauroyl Lysine, Phenoxyethanol, Water (Aqua), Sodium Dehydroacetate, Ascorbyl palmitate, Ceteareth-25, Glycerin, Cetyl Alcohol, Cholesterol, Ceramide NP, Behenic Acid, Ethylhexyglycerin, Ceramide NS, Ceramide AP, Ceramide EOP, Ceramide EOS, Caprooyl Pytosphingosine, Caprooyl Sphingosine, Tocopherol, Titanium Dioxide (CI77891), Iron Oxides (CI 77491)

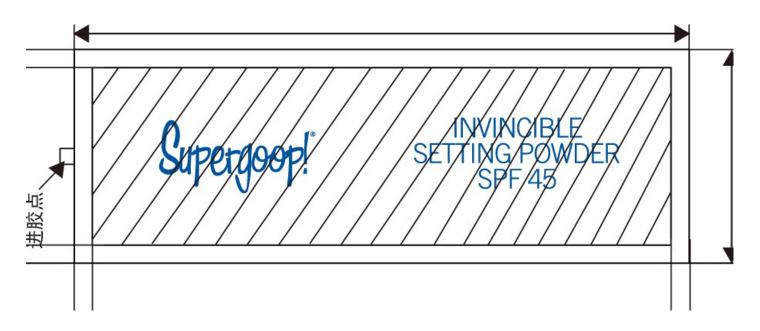
Invincible Setting Powder

**SPF 45** 

100% mineral. Sweat Resistant

0.09 oz / 2.5 g





### **INVINCIBLE SETTING POWDER SPF 45**

titanium dioxide, zinc oxide powder

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75936-105	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	15.7 g in 100 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)		
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)		
LAURO YL LYSINE (UNII: 113171Q70B)		
PHENO XYETHANOL (UNII: HIE492ZZ3T)		
WATER (UNII: 059QF0KO0R)		
SODIUM DEHYDRO ACETATE (UNII: 8 W46 YN971G)		
ASCORBYL PALMITATE (UNII: QN83US2B0N)		
CETEARETH-25 (UNII: 8FA93U5T67)		
GLYCERIN (UNII: PDC6A3C0OX)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
CHOLESTEROL (UNII: 97C5T2UQ7J)		
CERAMIDE NP (UNII: 4370 DF0 50 B)		
BEHENIC ACID (UNII: H390488X0A)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
CERAMIDE NG (UNII: C04977SRJ5)		

Ceramide AP (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
N-HEXANO YLSPHINGO SINE (UNII: 038753E78J)	
.ALPHATO COPHEROL (UNII: H4N855PNZ1)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

ı	Packaging				
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 N	DC:75936-105-01	4.5 g in 1 PACKAGE; Type 0: Not a Combination Product	0 1/13/20 17	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	0 1/13/20 17		

## Labeler - TAYLORJAMES, LTD. (033381850)

### **Registrant -** TAYLORJAMES, LTD. (033381850)

Establishment				
Name	Address	ID/FEI	Business Operations	
Kolmar Laboratories, Inc.		001535103	manufacture(75936-105)	

Revised: 1/2017 TAYLOR JAMES, LTD.