INVINCIBLE SETTING POWDER SPF 45 MEDIUM- 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.

Invincible Setting Powder SPF 45 Medium

Active ingredients Purpose

Zinc Oxide 24.5% 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.

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

Stop use and ask a doctor if rash occurs

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.

Directions

- apply generously and evenly 15 minutes before sun exposure
- reapply
- after 40 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **Sun Protection Measures** DSpending 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 15 or higher and other sun protections measures including:
- Limit time in the sun, especially from 10a.m. -2p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

Inactive Ingredients

Calcium Aluminum Borosilicate, Silica, Polymethyl Methacrylate, Ethylhexylglycerin, Triethoxycaprylysilane, Nylon-6/12, Sodium Dehydroacetate, Olive Glycerides, Ascorbyl Palmitate, Ceramide 3. May contain +/- Iron Oxides (CI 77492, CI 77491, CI 77499), Titanium Dioxide (CI 77891)

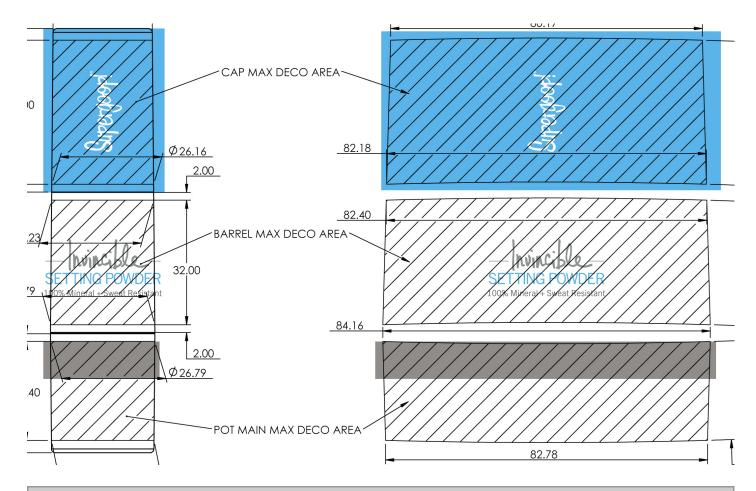
Invincible Setting Powder SPF 45

100% Mineral + Sweat resistant

Medium

0.15 oz./ 4.25 g





INVINCIBLE SETTING POWDER SPF 45 MEDIUM

zinc oxide powder

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:	NDC:75936-147	
Route of Administration	TOPICAL					
Active Ingredient/Active Mo	iety					
Ingredient Name			Basis of Streng	gth	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE					24.5 g in 100 g	
Inactive Ingredients						
Inactive Ingredients	Ingradiant Nama				Strongth	
	Ingredient Name				Strength	
CALCIUM ALUMINUM BOROSILIC	ATE (UNII: 3JRB8A35M0)				Strength	
CALCIUM ALUMINUM BOROSILICA SILICON DIOXIDE (UNII: ETJ7Z6XB)	ATE (UNII: 3JRB8A35M0) U4))			Strength	
CALCIUM ALUMINUM BOROSILIC SILICON DIOXIDE (UNII: ETJ7Z6XB POLY(METHYL METHACRYLATE;	ATE (UNII: 3JRB8A35M0) U4) 450000 MW) (UNII: Z47NNT4J1)			Strength	
CALCIUM ALUMINUM BOROSILICA SILICON DIOXIDE (UNII: ETJ7Z6XB) POLY(METHYL METHACRYLATE; ETHYLHEXYLGLYCERIN (UNII: 1471	ATE (UNII: 3JRB8A35M0) U4) 450000 MW) (UNII: Z47NNT4J1: D247K3P))			Strength	
CALCIUM ALUMINUM BOROSILIC SILICON DIOXIDE (UNII: ETJ7Z6XB POLY(METHYL METHACRYLATE; ETHYLHEXYLGLYCERIN (UNII: 1471 TRIETHOXYCAPRYLYLSILANE (UN	ATE (UNII: 3JRB8A35M0) U4) 450000 MW) (UNII: Z47NNT4J1 D247K3P) NII: LDC331P08E))			Strength	
CALCIUM ALUMINUM BOROSILIC	ATE (UNII: 3JRB8 A35M0) U4) 450000 MW) (UNII: Z47NNT4J1: D247K3P) VII: LDC331P08E) 8W46 YN971G))			Strength	

	ts			
Ingredient Kind		Ingredient Na	Quantity	
May contain		FERRIC OXIDE RED (UNII: 1K09F3G675)		
May contain		FERRIC OXIDE YELLOW (UNII: EX438O2MR)		
May contain		FERROSOFERRIC OXIDE (UNII: XM0 M87F35		
May contain		TITANIUM DIO XIDE (UNII: 15FIX9V2JP)		
Packaging				
# Item Code		Package Description	Marketing Start Date	Marketing End Dat
	1 in 1 BOX		Marketing Start Date 0 1/15/20 18	Marketing End Dat
1 NDC:75936-147-02			C C	Marketing End Dat
1 NDC:75936-147-02			C C	Marketing End Dat
1 NDC:75936-147-02			C C	Marketing End Dat
 1 NDC:75936-147-02 1 NDC:75936-147-01 	4.25 g in 1	PACKAGE; Type 0: Not a Combination Product	C C	Marketing End Dat
1 NDC:75936-147-02	4.25 g in 1	PACKAGE; Type 0: Not a Combination Product	C C	Marketing End Dat
 NDC:75936-147-02 NDC:75936-147-01 	4.25 g in 1 ormati	PACKAGE; Type 0: Not a Combination Product	C C	Marketing End Dat

Labeler - TAYLOR JAMES, LTD. (033381850)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Laboratories, Inc.		001535103	manufacture(75936-147)

Revised: 1/2018

TAYLOR JAMES, LTD.