

PURMINERALS 4 IN 1 MAKEUP SPF 15 TAN - titanium dioxide powder
PUR MINERALS

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.

Active Ingredient : Titanium Dioxide 9 %

Purpose : Sunscreen

Stop Use and Ask a Doctor : If rash or irritation develops and lasts.

Keep Out of Reach of Children . If swallowed , get medical help or contact a Poison Control Center right away.

Inactive Ingredients : Mica , Boron Nitride , Caprylic/Capric Triglyceride , Bismuth Oxochloride , Zinc Stearate , Magnesium Silicate , Magnesium Carbonate , Silica , Shea Butter (Butyrospermum Parkii) , Tocopheryl Acetate , Iron oxide , May contain ultramarines.

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67345-0631
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.72 g in 8 g

Inactive Ingredients

Ingredient Name	Strength
Mica (UNII: V8A1AW0880)	
Boron Nitride (UNII: 2U4T60A6YD)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
Bismuth Oxychloride (UNII: 4ZR792I587)	
Zinc Stearate (UNII: H92E6QA4FV)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
Shea Butter (UNII: K49155WL9Y)	
Acetate Ion (UNII: 569DQM74SC)	
Iron (UNII: E1UOL152H7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67345-0631-0	8 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/17/2006	

Labeler - PUR MINERALS (780516402)