CATRIN DIAMOND MINERAL FOUNDATION- titanium dioxide, zinc oxide powder Nature&Bio Co., 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.

ACTIVE INGREDIENT

Active ingredients: Titanium Dioxide 15.4%, Zinc Oxide 13%

INACTIVE INGREDIENT

Inactive ingredients: Mica, Bismuth Oxychloride, CI 77492, CI 77491, CI 77499, Quartz, Sapphire Powder, Diamond powder

PURPOSE

Purpose: Sunscreen

WARNINGS

Warnings:

For external use only. When using this product: Keep out of eyes, Rinse with water to remove. 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.

KEEP OUT OF REACH OF CHILDREN

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INDICATIONS & USAGE

Indications and usage: Helps prevent sunburn, Higher SPF gives more sunburn protection.

DOSAGE & ADMINISTRATION

Dosage and administration: Apply evenly before sun exposure as needed.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Image of carton



CATRIN DIAMOND MINERAL FOUNDATION

titanium dioxide, zinc oxide powder

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69058-010	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
Titanium Dioxide (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	Titanium Dioxide	1.38 g in 9 g			
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	1.17 g in 9 g			

Inactive Ingredients			
Ingredient Name	Strength		
Mica (UNII: V8A1AW0880)			

Packaging

#	Item Code	Package Description	Marketing	g Start Date	Mar	keting End Date
1 N	DC:69058-010-01	9 g in 1 CARTON				
Marketing Information						
M	arketing Category	Application Number or Monogr	aph Citation	Marketing Start	Date	Marketing End Date
OTO	monograph not final	art352		09/01/2014		

Labeler - Nature&Bio Co., Ltd. (690332858)

Registrant - Nature&Bio Co., Ltd. (690332858)

Establishment				
Name	Address	ID/FEI	Business Operations	
Nature&Bio Co., Ltd.		690332858	manufacture(69058-010)	

Revised: 1/2015 Nature&Bio Co., Ltd.