

SUNBLOCK - titanium dioxide lotion
Vienna Health and Beauty Corporation

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.

Drug Facts

Active Ingredients:	Purpose
Titanium Dioxide 8%	Sunscreen
Octyl Methoxycinnamate 6%	Sunscreen

Other Ingredients: Purified Water (Acqua), Caprylic/Capic Triglyceride, C12-15 Alkyl Benzoate, Glycerin, Cetyl Alcohol, Stearyl Alcohol, Isopropyl Myristate, Propylene Glycol, Ceteareth-6, Ceteareth-25, Dimethicone, Glyceryl Stearate, Stearic Acid, Tocopherol Acetate (Vitamin E), Alpha Bisabolol, Triethanolamine, Diazolidinyl Urea, Methylparaben, Propylparaben, Allantoin, BHT.

Vienna Health and Beauty - by Minh Le, M.D. SUNBLOCK - UVA/UVB Protection - SPF30



SUNBLOCK

titanium dioxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52625-101	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	6 g in 80 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	5 g in 80 g	
Inactive Ingredients				
Ingredient Name			Strength	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)				
GLYCERIN (UNII: PDC6A3C0OX)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
STEARYL ALCOHOL (UNII: 2KR89I4HIY)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
CETEARETH-25 (UNII: 8FA93U5T67)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
TROLAMINE (UNII: 9O3K93S3TK)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
ALLANTOIN (UNII: 344S277G0Z)				
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52625-101-02	1 in 1 CARTON		
1	NDC:52625-101-01	80 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		07/01/2010	

Labeler - Vienna Health and Beauty Corporation (831463919)

Registrant - Vienna Health and Beauty Corporation (831463919)

Establishment

Name	Address	ID/FEI	Business Operations
Vienna Health and Beauty Corporation		831463919	manufacture

Revised: 7/2010

Vienna Health and Beauty Corporation