

BUTTERMILK FUTURE RESIST FOUNDATION BROAD SPECTRUM SPF 20 DELILAH-titanium dioxide lotion

Delilah Cosmetics

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.

Buttermilk Future Resist Foundation Broad Spectrum SPF 20

Active Ingredients	Purpose
Titanium Dioxide 5%	Sunscreen

Uses

Helps prevent Sunburn

If used as directed with other sun protection measures (see Directions), decrease the risk of 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 foundation to a clean face for Broad Spectrum protection. Reapply as needed.

This is not a primary sunscreen. For further protection by a primary sunscreen follow directions below.

Apply primary sunscreen liberally 15 minutes before sun exposure

Reapply: At least 2 hours

Sun Protection Measures. Spending 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 SPF 15 or higher and other sun protection measures including:

Limit time in the sun, especially from 10 a.m. - 2p.m.

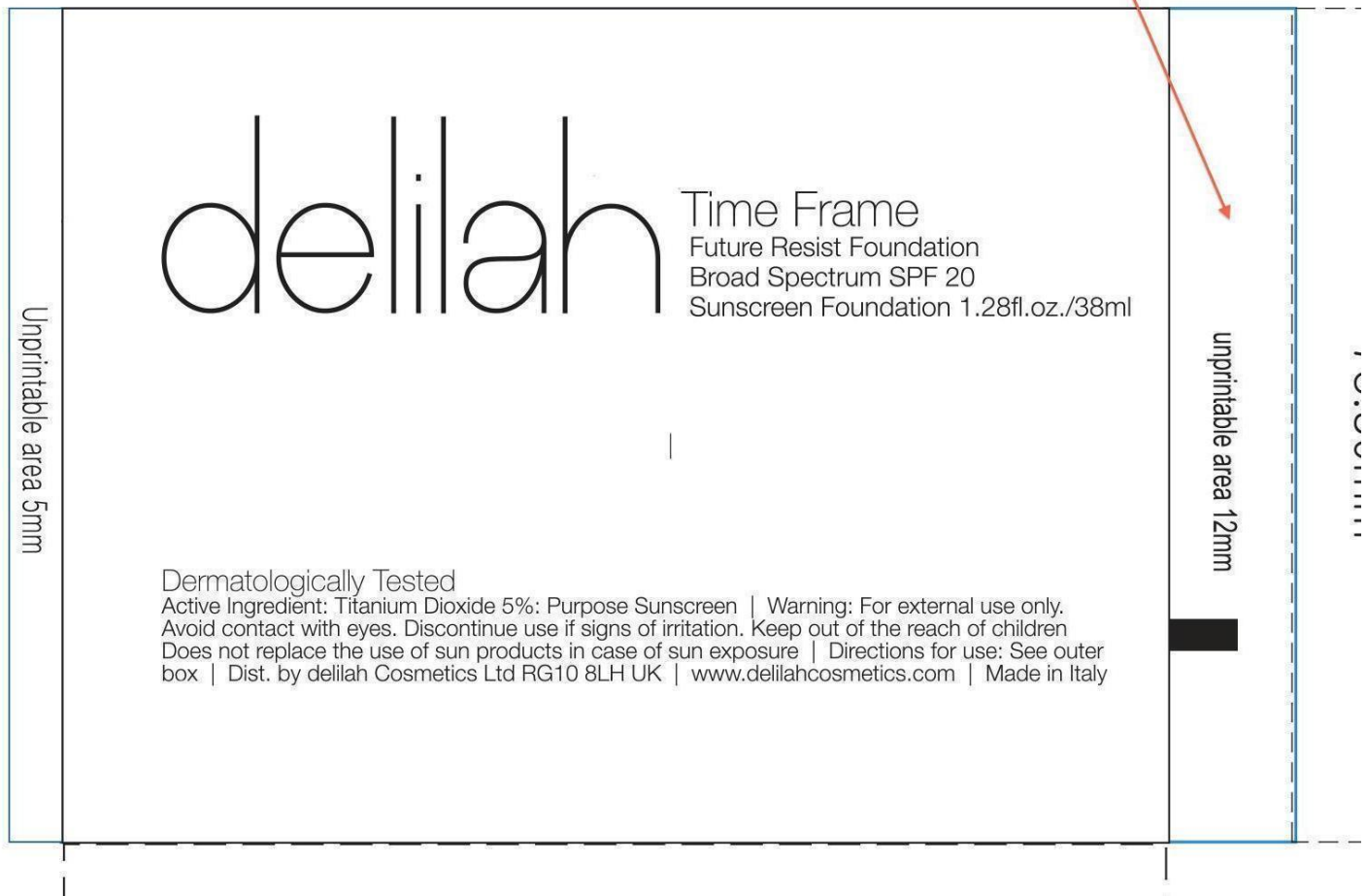
Wear long-sleeve shirts, pants, hats, and sunglasses

Children under 6 months ask doctor.

Inactive Ingredients: Water/Aqua, Cyclomethicone, Butylene Glycol, Isononyl Isononoate, Behenyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Phenyl Trimethicone, C12-15 Alkyl Benzoate, Distardimonium Hectorite, Glyceryl Ethylhexanoate/Stearate/Adipate, Phenoxyethanol, Sucrose Acetyl Isobutyrate, Tocopheryl Acetate, Sodium Chloride, Lauryl PEG-8 Dimethicone, Alumina, Sodium Dehydroacetate, Methicone, Triethoxycaprylylsilane, Caprylic/Capric Triglyceride, Trisodium Ethylenediamine Dissuccinate, Dimethicone, Tropolone, Tripeptide-3, Hexapeptide-3, (May contain (+/-) CI 77891 (Titanium Dioxide), CI 77491 (iron oxides), CI 77492 (Iron Oxides), CI 77499 (Iron Oxides).

Delilah

Time Frame Future resist Foundation Broad Spectrum SPF 20 Buttermilk



**BUTTERMILK FUTURE RESIST FOUNDATION BROAD SPECTRUM SPF 20
 DELILAH**

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69000-020
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	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	

C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PHENOXYETHANOL (UNII: HE492ZZ3T)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
ALUMINUM OXIDE (UNII: LM26O6933)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
METHICONE (20 CST) (UNII: 6777U11MKT)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
DIMETHICONE (UNII: 92RU3N3Y1O)
TROPOLONE (UNII: 7L6DL16P1T)
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWIL)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69000-020-02	1 in 1 CARTON		
1	NDC:69000-020-01	38 mL in 1 PACKAGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/13/2014	

Labeler - Delilah Cosmetics (219906475)

Registrant - Delilah Cosmetics (219906475)

Establishment			
Name	Address	ID/FEI	Business Operations
Gotha Cosmetics SRL		378071679	manufacture(69000-020)