



Active Ingredient

Titanium Dioxide 3.57 %

Inactive Ingredients

Water, Propanediol, Phenyl Trimethicone, Dicaprylyl Carbonate, Methylpropanediol, Cyclomethicone, 1,2-Hexanediol, Glycereth-26, Methyl Trimethicone, Salvia Hispanica Seed Extract, Centella Asiatica Extract, Houlttuynia Cordata Extract, Polyglyceryl-2 Caprate, Methyl Methacrylate Crosspolymer, Sucrose Stearate, Fructooligosaccharides, Saccharide Hydrolysate, Simmondsia Chinensis (Jojoba) Seed Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cellulose Gum, Tromethamine, Hydroxypropyl Methylcellulose, Cetyl Hydroxyethylcellulose, Stearic Acid, Alumina, Betaine, Trehalose, Pullulan, Glyceryl Caprylate, Ethylhexylglycerin, Squalane, Butylene Glycol, Pentylene Glycol, Aloe Barbadensis Leaf Extract, Madecassoside, C12-15 Alkyl Benzoate, Sodium Hyaluronate, Aluminum Stearate, Polyhydroxystearic Acid

IM SAFE FOR BABY AND SILVER

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72284-0005
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	1.78 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
SALVIA HISPANICA SEED (UNII: NU0OLX06F8)	
FRUCTOSE (UNII: M7522JYX1H)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TROMETHAMINE (UNII: 023C2WHX2V)	
BETAINE (UNII: 3SCV180C9W)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
SQUALANE (UNII: GW89575KF9)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
MADECASSOSIDE (UNII: CQ2F5O6YIY)
INVERT SUGAR (UNII: ED959S6ACY)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
SUCROSE STEARATE (UNII: 274KW0O50M)
TREHALOSE (UNII: B8WCK70T7I)
PULLULAN (UNII: 8ZQ0AYU1TT)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
PROPANEDIOL (UNII: 5965N8W85T)
HYPROMELLOSES (UNII: 3NXW29V3WO)
STEARIC ACID (UNII: 4ELV7Z65AP)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
WATER (UNII: 059QF0KO0R)
GLYCERETH-26 (UNII: NNE56F2N14)
METHYL TRIMETHICONE (UNII: S73ZQI0GXM)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
HOULTTUYNIA CORDATA WHOLE (UNII: O3E12ZLW5T)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
ALUMINUM STEARATE (UNII: U6XF9NP8HM)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72284-0005-1	1 in 1 BOX	03/06/2019	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/06/2019	

Labeler - Normalest Co., Ltd. (694812877)

Registrant - Normalest Co., Ltd. (694812877)

Establishment

Name	Address	ID/FEI	Business Operations
Normalest Co., Ltd.		694812877	manufacture(72284-0005)

Revised: 3/2019

Normalest Co., Ltd.