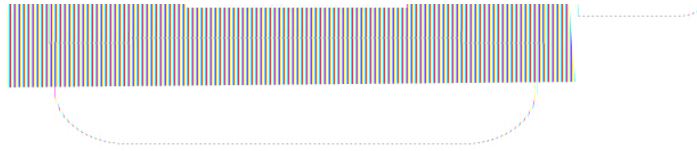


IM SAFE FOR SENSITIVE SKIN- titanium dioxide lotion
Normalest Co., Ltd.

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.

190422 선티크_ I'M SAFE FOR SENSITIVE SKIN





Active Ingredients

Titanium Dioxide

Inactive Ingredients

Water, Propanediol, Phenyl Trimethicone, Dicaprylyl Carbonate, Methylpropanediol, Cyclopentasiloxane, 1,2-Hexanediol, Glycereth-26, Methyl Trimethicone, Polyglyceryl-2 Caprate, Methyl Methacrylate Crosspolymer, Styrene/Acrylates Copolymer, Sucrose Stearate, Tromethamine, Simmondsia Chinensis (Jojoba) Seed Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Cellulose Gum, Hydroxypropyl Methylcellulose, Cetyl Hydroxyethylcellulose, Stearic Acid, Alumina, Betaine, Trehalose, Glyceryl Caprylate, Butylene Glycol, Pentylene Glycol, Ethylhexylglycerin, Squalane, Centella Asiatica Extract, Aloe Barbadosensis Leaf Extract, Madecassoside, Butylene Glycol Dicaprylate/Dicaprate, Carbomer, Polyacrylate Crosspolymer-6, t-Butyl Alcohol

IM SAFE FOR SENSITIVE SKIN

titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72284-0007
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	1.785 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
SUCROSE STEARATE (UNII: 274KW0 O50 M)	
BETAINE (UNII: 3SCV180 C9 W)	
TREHALOSE (UNII: B8 WCK70 T7 I)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4 A)	
PENTYLENE GLYCOL (UNII: 50 C1307 PZG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3 P)	
SQUALANE (UNII: GW89575KF9)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI0 15FF9)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
WATER (UNII: 059QF0KO0R)	

DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
PROPANEDIOL (UNII: 5965N8W85T)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
METHYLPROPANEDIOL (UNII: N8F53B3R4R)
METHYL TRIMETHICONE (UNII: S73ZQ10GXM)
JOJOBA OIL (UNII: 724GKU717M)
TROMETHAMINE (UNII: 023C2WHX2V)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
MADECASSOSIDE (UNII: CQ2F5O6YTY)
BUTYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: 75D21FL1PI)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)
HYPROMELLOSES (UNII: 3NXW29V3WO)
STEARIC ACID (UNII: 4ELV7Z65AP)
ALUMINUM OXIDE (UNII: LM26O6933)
GLYCERETH-26 (UNII: NNE56F2N14)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72284-0007-1	1 in 1 BOX	04/24/2019	
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	04/24/2019	

Labeler - Normalest Co., Ltd. (694812877)

Registrant - Normalest Co., Ltd. (694812877)

Establishment

Name	Address	ID/FEI	Business Operations
Normalest Co., Ltd.		694812877	manufacture(72284-0007)