

TINTED MINERAL SUNSCREEN STICK- titanium dioxide, zinc oxide stick
EDIT EUROSPA, LLC

Product packaging for Tinted Mineral Sunscreen Stick. Includes drug facts, ingredients, and usage instructions.

TINTED MINERAL SUNSCREEN STICK			
titanium dioxide, zinc oxide stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85642-220(NDC:58892-220)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	40 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	55 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
CETEARYL ISONONANOATE (UNII: P5O01U99NI)			
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)			
SOYBEAN LECITHIN (UNII: 1DI56QDM62)			
PEG-8 (UNII: B697894SGQ)			
CITRIC ACID (UNII: 2968PHW8QP)			
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
ALUMINA (UNII: LMI26O6933)			
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)			
ETHYLHEXYL PALMITATE (UNII: 2865993309)			

CI 77499 (UNII: XM0M87F357)	
CERESIN (UNII: Q1LS2UJO3A)	
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CI 77491 (UNII: 1K09F3G675)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CI 77492 (UNII: EX438O2MRT)	
DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER (UNII: R6G12EY23X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
HEXYLDECANOL (UNII: 151Z7P1317)	
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85642-220-30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	03/19/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/19/2025	

Labeler - EDIT EUROSPA, LLC (092857973)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85642-220)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85642-220)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85642-220)

