

TINTED LIP PROTECTION- titanium dioxide, zinc oxide stick
WECARE FRISCO PLLC



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TINTED LIP PROTECTION

titanium dioxide, zinc oxide stick

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:85747-212(NDC:58892-212)

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)

ZINC OXIDE

55 mg in 1 g

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 g
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Inactive Ingredients

Ingredient Name	Strength
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
HEXYLDECANOL (UNII: 151Z7P1317)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)	
DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER (UNII: R6G12EY23X)	
CI 77491 (UNII: 1K09F3G675)	
PEG-8 (UNII: B697894SGQ)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
CI 77499 (UNII: XM0M87F357)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)	
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)	
CITRIC ACID (UNII: 2968PHW8QP)	
CI 77492 (UNII: EX438O2MRT)	
ALUMINA (UNII: LMI26O6933)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CERESIN (UNII: Q1LS2UJO3A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	KIWI, LIME	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85747-212-45	1 in 1 CARTON	11/16/2022	
1		4.5 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/16/2022	

Labeler - WECARE FRISCO PLLC (069012846)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85747-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85747-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85747-212)

Revised: 12/2025

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