

LIPBOMB- titanium dioxide, zinc oxide stick
FLEUR DE VIE LLC



LIPBOMB

titanium dioxide, zinc oxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85635-212
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	38 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	40 mg in 1 g
Inactive Ingredients			

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

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:85635-212-45	4.5 in 1 CYLINDER	11/08/2019	
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	11/08/2019	

Labeler - FLEUR DE VIE LLC (080773694)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85635-212)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85635-212)

Revised: 6/2025

FLEUR DE VIE LLC