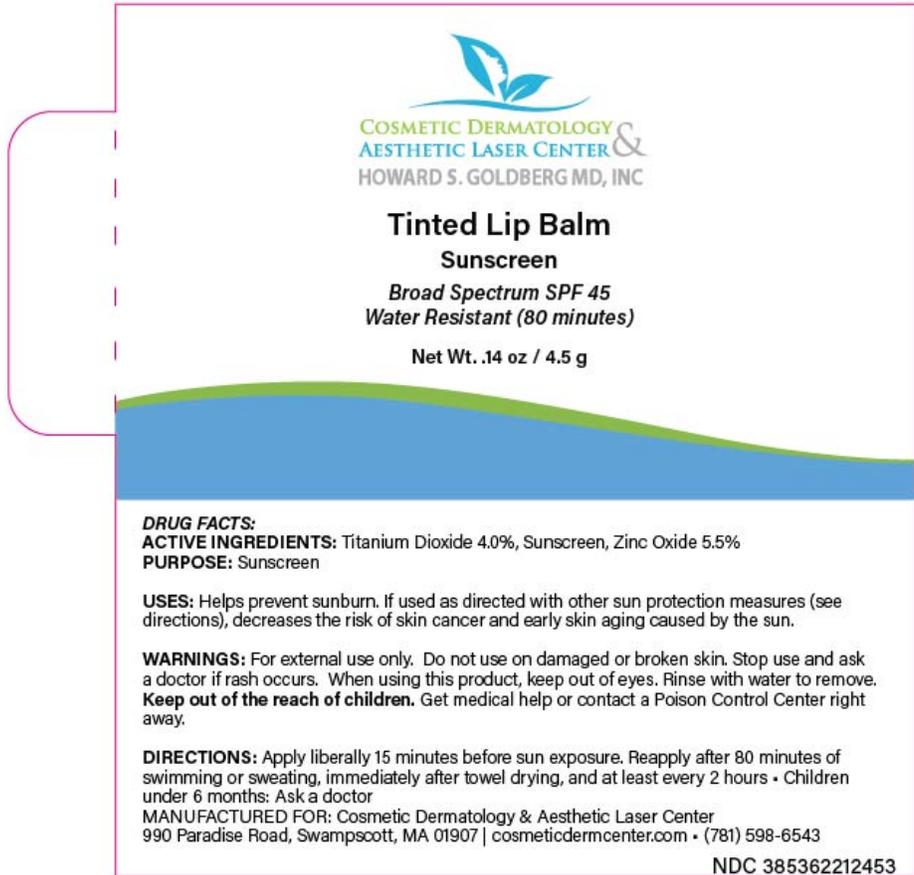


TINTED LIP BALM- titanium dioxide, zinc oxide stick
Goldberg, Howard S MD Inc

Tinted Lip Balm
 Sunscreen

Broad Spectrum SPF 45
 Water Resistant (80 minutes)
 Net Wt. .14 oz / 4.5 g



COSMETIC DERMATOLOGY & AESTHETIC LASER CENTER
 HOWARD S. GOLDBERG MD, INC

Tinted Lip Balm
 Sunscreen

Broad Spectrum SPF 45
Water Resistant (80 minutes)

Net Wt. .14 oz / 4.5 g

DRUG FACTS:
ACTIVE INGREDIENTS: Titanium Dioxide 4.0%, Sunscreen, Zinc Oxide 5.5%
PURPOSE: Sunscreen

USES: Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin aging caused by the sun.

WARNINGS: For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. **Keep out of the reach of children.** Get medical help or contact a Poison Control Center right away.

DIRECTIONS: Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating, immediately after towel drying, and at least every 2 hours • Children under 6 months: Ask a doctor

MANUFACTURED FOR: Cosmetic Dermatology & Aesthetic Laser Center
 990 Paradise Road, Swampscott, MA 01907 | cosmeticdermcenter.com • (781) 598-6543

NDC 385362212453



TINTED LIP BALM			
titanium dioxide, zinc oxide stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85362-212(NDC:58892-212)
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
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
PEG-8 (UNII: B697894SGQ)	
CITRIC ACID (UNII: 2968PHW8QP)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
HEXYLDECANOL (UNII: 151Z7P1317)	
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
CERESIN (UNII: Q1LS2UJO3A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)	
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
CI 77492 (UNII: EX438O2MRT)	
ALUMINA (UNII: LMI26O6933)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER (UNII: R6G12EY23X)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	

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:85362-212-45	4.5 g in 1 CYLINDER; Type 0: Not a Combination Product	01/07/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/07/2025	

Labeler - Goldberg, Howard S MD Inc (181591181)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85362-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85362-212)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85362-212)

Revised: 12/2025

Goldberg, Howard S MD Inc