

**REALLY GREAT LIP SHIELD- titanium dioxide, zinc oxide stick**  
**JEFFREY J. ROTH, M.D., A PROFESSIONAL CORPORATION**

Really Great Lip Shield

Tinted Lip Sunscreen  
**Broad Spectrum SPF 45**  
 Water Resistant (80 minutes)  
 net wt. .14 oz / 4.5 g



RothMD  
 Medical Grade Sunscreen

Really Great Lip Shield

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 Water Resistant  
 (80 minutes)

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**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:** Jeffrey J. Roth, M.D., F.A.C.S • Las Vegas, NV 89148

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NDC: 8558521245

RothMD  
 Medical Grade Sunscreen  
**Really Great Lip Shield**  
 MINERAL SUNSCREEN  
 SPF 45

**REALLY GREAT LIP SHIELD**

titanium dioxide, zinc oxide stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:85585-212(NDC:58892-212)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	55 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 g

## Inactive Ingredients

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

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	LIME, KIWI	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85585-212-45	1 in 1 CARTON	05/26/2022	
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	05/26/2022	

**Labeler** - JEFFREY J. ROTH, M.D., A PROFESSIONAL CORPORATION (557562910)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85585-212)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85585-212)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85585-212)

Revised: 12/2025

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