

SPF 30 LIP BALM- titanium dioxide stick
Malin and Goetz Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

spf 30 Lip Balm

Active Ingredient Purpose

Titanium Dioxide 3.32% 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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Stop use and ask a doctor

- If rash occurs

Warnings

For external use only

Do not use on damaged or broken skin

When using this product

- Keep out of eyes. Rinse with water to remove

Directions

- Apply Liberally and evenly 15 minutes before sun exposure
- Children under 6 months of age: Ask a doctor

Sun Protection Measures

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- Limit time in the sun especially from 10 am- 2pm
- Wear long-sleeved shirts, pants, hats & sunglasses
- Reapply after 40 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours

Other information

- Protect the product in this container from excessive heat and direct sun

Inactive Ingredients

Hydrogenated Polyisobutene, Ethylhexyl Palmitate, Hydrogenated Styrene/Isoprene

Copolymer, Hydrogenated Polydecene, Flavor, Cinnamal, Cinnamyl Alcohol, Coumarin, d-Limonene, Eugenol, Methyl 2 Octynoate, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Urolic Acid, Tocopherol, Stearic Acid, Aluminum Hydroxide.

(Malin+Goetz)

spf 30 lip balm.

Broad Spectrum Mineral Sunscreen

Water Resistant 40 minutes

0.3fl. oz./10ml

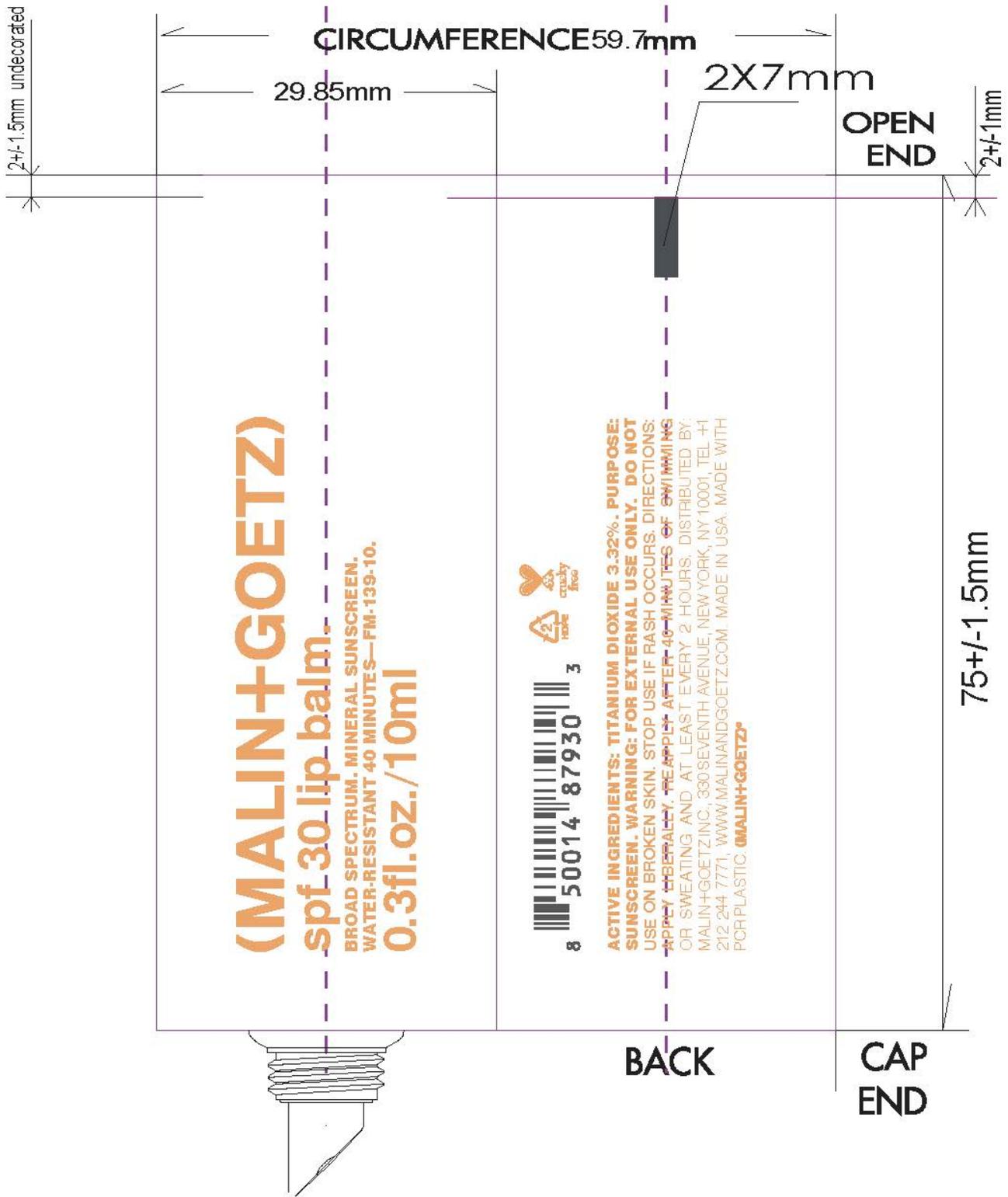
(MALIN+GOETZ)

slug/specs for vendors.

ARTWORK BREAKDOWN FOR PRODUCTION.
TRANSLATION — SKU NUMBER.
measurements.

SKU: SPF 30 LIP BALM, US + CA VERSION.
CATEGORY: FACE.
FONTS USED: SANS 721 FAMILY.
APPLICATION USED: ADOBE ILLUSTRATOR CC.
COLORS: PMS 804 C ■ PMS 7540 C ■





SPF 30 LIP BALM

titanium dioxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53634-129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CINNAMYL ALCOHOL (UNII: SS8YOP444F)	
EUGENOL (UNII: 3T8H1794QW)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
METHYL HEPTINE CARBONATE (UNII: 0TTP6YT2T3)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
COUMARIN (UNII: A4VZ22K1WT)	
TOCOPHEROL (UNII: R0ZB2556P8)	
URSOLIC ACID (UNII: P3M2575F3F)	
CINNAMALDEHYDE (UNII: SR60A3XG0F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53634-129-01	10 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	05/01/2023	

Labeler - Malin and Goetz Inc (138615930)

Revised: 6/2023

Malin and Goetz Inc