

**STANDARD PROCEDURE LIP BALM SPF 50- zinc oxide homosalate
octocrylene stick
Standard Procedure Inc**

Active Ingredients

Zinc Oxide 8%
Homosalate 6%
Octocrylene 3%

Helps prevent sunburn

If used as directed with other sun protection measures (see **Directions**), decrease the risk of skin cancer and early skin aging caused by the sun

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 reach of children

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

Directions

Apply generously and evenly 15 minutes before sun exposure • reapply at least every 80 minutes • use a water resistant sunscreen if swimming or sweating

• 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 broad spectrum SPF of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses

• Children under 6 months: Ask a doctor

Other Information

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

Inactive Ingredients

Ricinus Communis (Castor) Seed Oil, Caprylic/capric Triglyceride, Ozokerite, C12-15 Alkyl Benzoate, Butyrospermum Parki (Shea) Butter, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Tribehenin, Silica Dimethyl Silylate, Polyglyceryl-3 Polyricinoleate, Bis-Ethyhexyloxyphenol Methoxyphenyl Triazine, Flavor, Triacontanyl Pup, Tocopheryl Acetate, Stevia Rebaudiana Leaf

Package Label. Principal Display Panel



Standard Procedure

Lipbalm SPF 50+

Coconut

Broad Spectrum UVA/UVB

5g 0.17oz.

IMAGE Lip Balm 240410.jpg

STANDARD PROCEDURE LIP BALM SPF 50

zinc oxide homosalate octocrylene stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84425-105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	60 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	30 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
BEMOTRIZINOL (UNII: PWZ1720CBH)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
STEVIA REBAUDIANA LEAF (UNII: 6TC6NN0876)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
RICINUS COMMUNIS SEED (UNII: 7EK4SFN1TX)	
CERESIN (UNII: Q1LS2UJO3A)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84425-105-05	5 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/22/2024	

Labeler - Standard Procedure Inc (119276141)