

**BIORLX LIP BALM GINSENG- avobenzone, mineral oil, octinoxate, petrolatum, zinc oxide stick
LOTUSA LLC.**

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.

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- a. Avobenzone 1.0%w/w
 - b. Mineral Oil 30.0%w/w
 - c. Octinoxate 6.0% w/w
 - d. Petrolatum 30.0% w/w
 - e. Zinc Oxide 6.0% w/w
 - f. Aloe Barbadensis (Alove Vera) Leaf Juice
 - g. Beeswax
 - h. Butyrospermum (Shea) Parkii Butter
 - i. Curcuma Longa (Turmeric) Root Extract
 - j. Caprylic/ Capric Triglyceride
 - k. Ceresin
 - l. Microcrystalline Wax
 - m. Potassium Sorbate
 - n. Tocopherol
 - o. Panax Ginseng (Ginseng) Root Extract

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Avobenzone 1.0% w/w Sunscreen
Mineral Oil 30.0% w/w Skin protectant
Octinoxate 6.0% w/w Sunscreen
Petrolatum 30.0% w/w Skin protectant
Zinc Oxide 6.0% w/w Sunscreen

Purpose

Sunscreen, Skin protectant, Lip Balm

Use

Helps prevent sunburn if use as directed with other sun protection measures.
provides moderate protection against sunburn
Helps temporarily protect chapped and cracked lips.

Warnings

For external use only.

Do not use

- in children less than 6 months of age on damaged or broken skin
- if you are allergic to any ingredients

When using this product do not get into eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if rash or irritation develops and lasts.

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

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Directions

Apply as needed. Apply liberally 15 minutes before sun exposure. Reapply after 60 minutes of swimming or sweating, immediately after towel drying at least every 2 hours. For best results use daily.

Other information

- Spending time in the sun increases your risk of skin cancer and early aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other long-sleeve shirts, pants or hats and sunglasses.
Store at room temperature

Inactive ingredients

Aloe Barbadensis (Aloe Vera) Leaf Juice, Beeswax, Butyrospermum (Shea) Butter, Caprylic/Capric Triglyceride, Ceresin, Curcuma Longa (Turmeric) Root Extract, Microcrystalline Wax, Panax Ginseng (Ginseng) Root Extract, Potassium Sorbate, Tocopherol

Package Label - Principal Display Panel

12x3.5 g NDC: 80554-003-01



BIORLX LIP BALM GINSENG

avobenzone, mineral oil, octinoxate, petrolatum, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80554-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 g in 100 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	30 g in 100 g
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	30 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
WHITE WAX (UNII: 7G1J5DA97F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CERESIN (UNII: Q1LS2UJO3A)	
CURCUMA LONGA LEAF (UNII: H2HC4RY52C)	
PANAX GINSENG ROOT OIL (UNII: P9T4K47OM0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80554-003-02	12 in 1 BOX	09/01/2020	
1	NDC:80554-003-01	3.5 g in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/30/2020	

Labeler - LOTUSA LLC. (122415153)**Registrant** - LOTUSA LLC. (122415153)**Establishment**

Name	Address	ID/FEI	Business Operations
FRENCH MALIHOME PERSONAL PRODUCTS LIMITED		664283791	manufacture(80554-003)

Revised: 9/2020

LOTUSA LLC.