

**BIORLX LIP BALM HEMP- avobenzene, 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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This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Avobenzene 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. Butyrpsoermum (Shea) Parkii Butter
- i. Cannabis Sativa (Hemp) Seed Oil
- j. Caprylic/ Capric Triglyceride
- k. Ceresin
- l. Microcrystalline Wax
- m. Potassium Sorbate
- n. Tocopherol

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)**

Avobenzene 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.

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.

## **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, Cannabis Sativa (Hemp) Seed Oil, Caprylic/ Capric Triglyceride, Ceresin, Microcrystalline Wax, Potassium Sorbate, Tocopherol

## **Package Label - Principal Display Panel**

3.5g x 12 NDC: 80554-001-01



SUNSCREEN  
LIP PROTECTANT

moisturizes and protects lips

**BioRLX** HEMP & ALOE LIP BALM

Nourishing  
Restoring  
Smoothing

**Drug Facts**

Active Ingredients	Purpose
Avobenzone 3.0% w/w	Sunscreen
Homosalate 10.0% w/w	Skin protectant
Octinoxate 6.0% w/w	Sunscreen
Petrolatum 10.0% w/w	Skin protectant
Zinc Oxide 2.0% w/w	Sunscreen

**Other Ingredients**

Includes: Vitamin E, Aloe Vera, and other natural ingredients.

**Directions**

Apply as needed. Apply 15-30 minutes before sun exposure. Reapply every 2 hours, immediately after towel drying or when sweating. For best results, use after meals.

**Warnings**

For external use only.

Do not use if you are allergic to any of the ingredients.

Keep out of reach of children. If swallowed, get medical help or contact poison control center or your doctor. Do not use if you are pregnant or breastfeeding.

**Other Information**

Keep out of reach of children. If swallowed, get medical help or contact poison control center or your doctor. Do not use if you are pregnant or breastfeeding.

**How to use**

Apply as needed. Apply 15-30 minutes before sun exposure. Reapply every 2 hours, immediately after towel drying or when sweating. For best results, use after meals.

**Keep out of reach of children. If swallowed, get medical help or contact poison control center or your doctor. Do not use if you are pregnant or breastfeeding.**

**How to use**

Apply as needed. Apply 15-30 minutes before sun exposure. Reapply every 2 hours, immediately after towel drying or when sweating. For best results, use after meals.

**Keep out of reach of children. If swallowed, get medical help or contact poison control center or your doctor. Do not use if you are pregnant or breastfeeding.**

**How to use**

Apply as needed. Apply 15-30 minutes before sun exposure. Reapply every 2 hours, immediately after towel drying or when sweating. For best results, use after meals.

**Keep out of reach of children. If swallowed, get medical help or contact poison control center or your doctor. Do not use if you are pregnant or breastfeeding.**

Net: 3.5g (0.12oz)

Made in Hong Kong  
Batch No.: HMP 01

**HEMP & ALOE LIP BALM**

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Cherished by  
Soleo para uso externo. Suspéndase su uso si se produce eritema o irritación. Evitar contacto visual. Mantener en un lugar fresco y seco, lejos del alcance de los niños. El contenido del producto, el número de lote y la fecha de vencimiento están en el paquete.

Seit für den externen Gebrauch. Bei Hautirritation oder Rötung absetzen. Vermeiden Sie Augenkontakt. In einem kühlen, trockenen Ort lagern. Halten Sie das Produkt von Kindern fern. Inhalt, Losnummer und Verfallsdatum sind auf der Verpackung.

For external use only. Stop using if redness or irritation occurs. Avoid contact with eyes. Keep in a cool, dry place. Do not use if you are allergic to any of the ingredients. The content of the product, the number of lot or fabrication date is on the packaging.

1. Hidrata y protege los labios / "Nourishes" - "Restauradora" - "Santificante"  
2. Sans Tric & sans drogue  
3. D'origine naturelle / "Natural" - "Nourissant" - "Régénérant"  
4. Hydrate et protège les lèvres / "Nourissant" - "Régénérant" - "Santifiant"  
5. Gives lips a light natural-looking sheen  
6. Moisturizes and protects lips / "Nourishing" - "Restoring" - "Smoothing"

**BioRLX** HEMP & ALOE LIP BALM

Nourishing  
Restoring  
Smoothing

With ALOE

PARABEN FREE  
COLOR FREE

SPF 15

**HEMP & ALOE LIP BALM**

PARABEN FREE  
COLOR FREE

SPF 15

**BIORLX LIP BALM HEMP**  
avobenzone, mineral oil, octinoxate, petrolatum, zinc oxide stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80554-001
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	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
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WHITE WAX (UNII: 7G1J5DA97F)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CERESIN (UNII: Q1LS2UJO3A)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80554-001-02	12 in 1 BOX	09/01/2020	
1	NDC:80554-001-01	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
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FRENCH MALIHOME PERSONAL PRODUCTS LIMITED		664283791	manufacture(80554-001)
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Revised: 9/2020

LOTUSA LLC