BIORLX LIP BALM COLLAGEN- 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.

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. 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. Butyrpsoermum (Shea) Parkii Butter

i.Caprylic/ Capric Triglyceride

j. Ceresin

k.Collagen

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)

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 keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
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 sweatig, immediately after towel drying at leaft every 2 hours. For best results use daily.

Other information

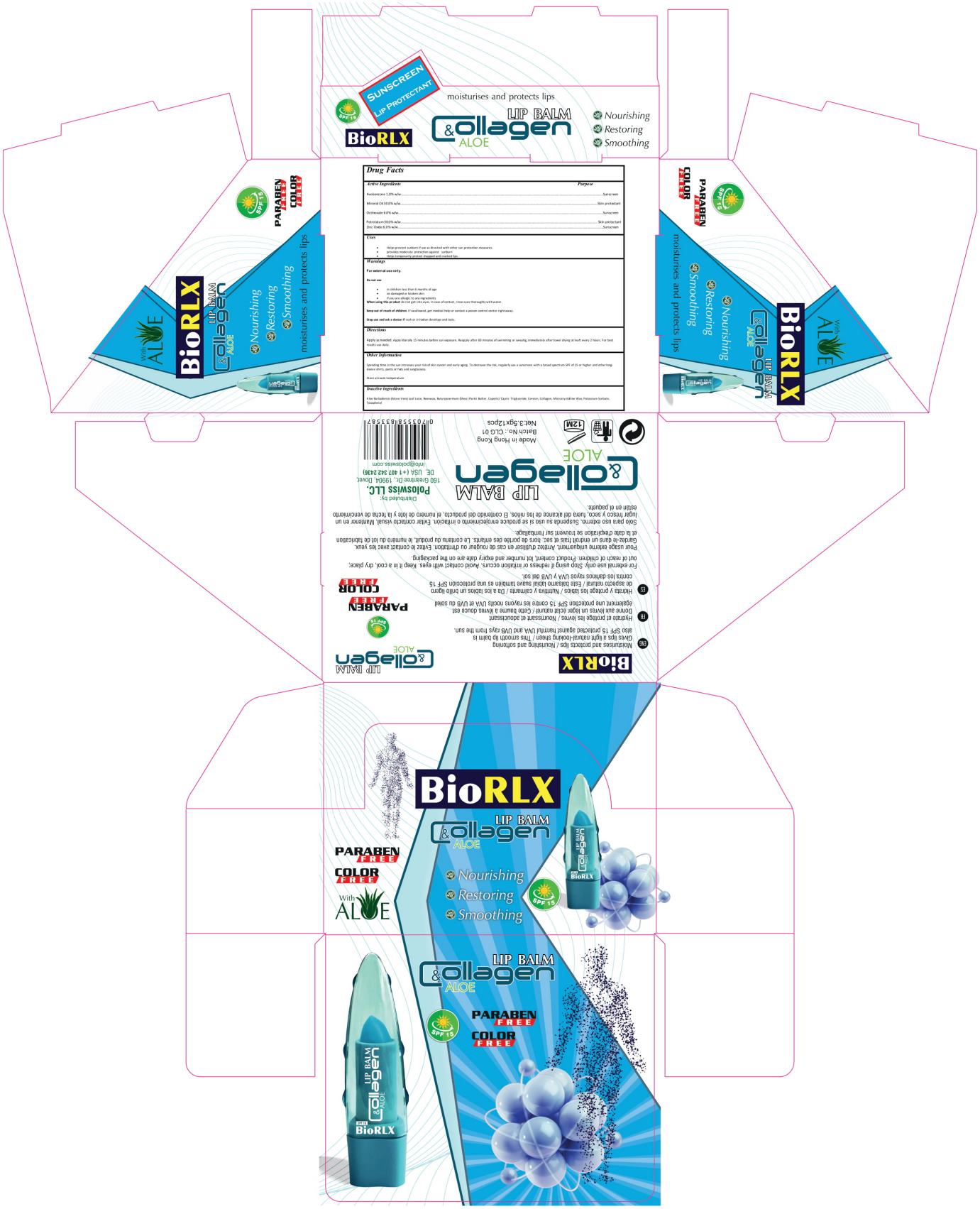
- Spending time in the sun increases your risk of skin cancer and early aging. To decrease the risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other longsleeve shirts, pants or hats and sunglassess.
  Store at room temperature

Inactive ingredients

Aloe Barbadensis (Alove Vera) Leaf Juice, Beeswax, Butyrpsoermum (Shea) Parkii Butter, Caprylic/ Capric Triglyceride, Ceresin, Collagen, Microcrystalline Wax, Potassium Sorbate, Tocopherol

Package Label - Principal Display Panel

12x3.5 g NDC:80554-002-01



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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80554-002
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
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

Inactive Ingredients	
Ingredient Name	**Strength**
WHITE WAX (UNII: 7G1J5DA97F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
COLLAGEN ALPHA-1(I) CHAIN BOVINE (UNII: FB3DQM32F2)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CERESIN (UNII: Q1LS2UJO3A)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80554-002-02	12 in 1 BOX	09/01/2020	
1	NDC:80554-002-01	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(80554-002)