

## **59ML LYCHEE ROSE HAND SANITIZER- alcohol gel MISTRAL**

*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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### **MISTRAL - 59ml Lychee Rose Hand sanitizer**

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

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)**

Ethyl Alcohol 74%

### **Purpose**

Antiseptic

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

on open skin wounds - around eyes - in ears and mouth

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.

### **Directions**

- Wet hands thoroughly with product and allow to dry without wiping.
- Supervise children under 6 years of age when using this product to avoid swallowing.
- Not recommended for infants

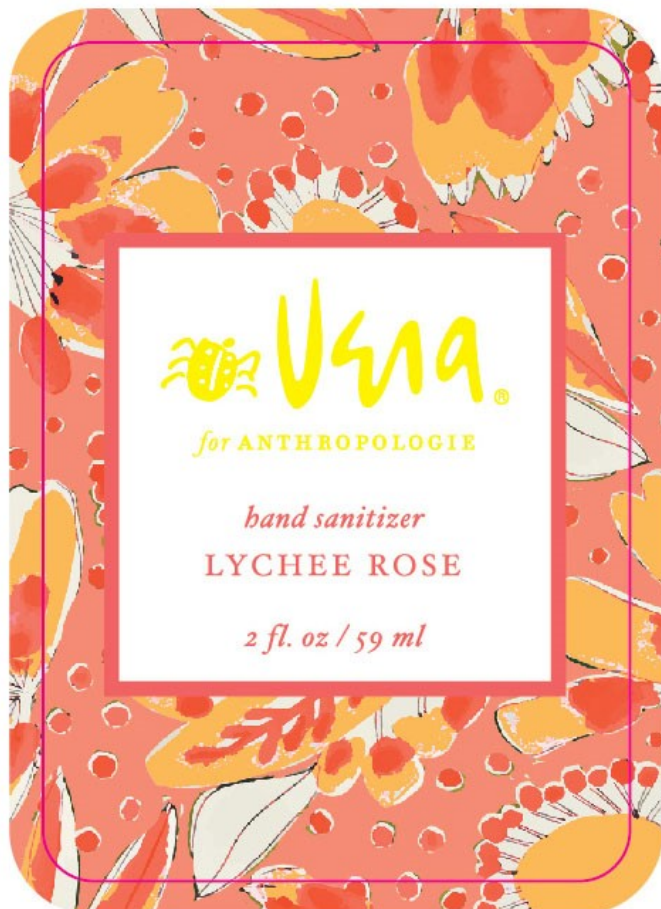
### **Other information**

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- May discolor some fabrics
- Harmful to wood finishes and plastics

### **Inactive ingredients**

Aqua (Water), Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Parfum (Fragrance), Triethanolamine, Aloe Barbadensis Leaf Juice Powder

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



## LYCHEE ROSE *hand sanitizer*

### Drug Facts

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Ethyl Alcohol 74% . . Antiseptic

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### Drug Facts (continued)

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MADE IN FRANCE



## 59ML LYCHEE ROSE HAND SANITIZER

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80859-012
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	74 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	0.15 mL in 100 mL
<b>ALOE</b> (UNII: V5VD430YW9)	0.0005 mL in 100 mL
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	5 mL in 100 mL
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	0.5 mL in 100 mL
<b>WATER</b> (UNII: 059QF0KO0R)	19.9495 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80859-012-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2021	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	02/22/2021	

**Labeler** - MISTRAL (849997700)

Revised: 2/2021

MISTRAL