

## **SOUTH SEAS 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 - South Seas 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 Barbadosensis Leaf Juice Powder

### Package Label - Principal Display Panel

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Ethyl Alcohol 74% . . . . .	Antiseptic
<b>Use(s)</b>	
Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<b>Warnings</b>	
<b>For external use only. Flammable. Keep away from heat or flame.</b>	
<b>Do not use</b>	
• on open skin wounds • around eyes • in ears and mouth	
<b>When using this product</b> keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
<b>Stop use and ask a doctor</b> if irritation or rash occurs. These may be signs of a serious condition.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	

<b>Drug Facts (continued)</b>
<b>Directions</b>
• 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
<b>Other information</b>
• Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) • May discolor some fabrics • Harmful to wood finishes and plastics
<b>Inactive Ingredients</b> Aqua (Water), Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Parfum (Fragrance), Triethanolamine, Aloe Barbadosensis Leaf Juice Powder
Distributed by Mistral LLC, Carlsbad, CA 92011 Toll free: 1.866.MISTRAL MISTRALSOAP.COM MADE IN FRANCE
 7 51305 00752 1

50 mL NDC: 80859-002-01

**SOUTH SEAS HAND SANITIZER**  
alcohol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80859-002
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<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**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:80859-002-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2021	

**Marketing Information**

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

**Labeler - MISTRAL (849997700)**

Revised: 2/2021

MISTRAL