

SOUTH SEAS HAND SANITIZER- alcohol gel LABORATOIRES BEA

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.

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

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Drug Facts (continued)
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Distributed by Mistral LLC, Carlsbad, CA 92011 Toll free: 1.866.MISTRAL MISTRALSOAP.COM MADE IN FRANCE
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SOUTH SEAS HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74819-0002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74819-0002-1	50 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 - LABORATOIRES BEA (772471215)

Revised: 2/2021

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