

HAND SANITIZER- ethyl alcohol spray
San Marino Beauty Inc.

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.

Olecea Hand Sanitizer Application

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. Isopropyl Alcohol (75%, 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 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

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

- in children less than 2 months of age
- on open skin wounds

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.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

OLECEA BEAUTE

Hand Sanitizer
Alcohol Antiseptic 70% Topical Solution

Non-sterile Solution

59ml / 2.0 fl oz

Drug Facts

Active Ingredient	Purpose
Ethyl Alcohol 70% (v/v)	Antiseptic

Warning

- For external use only.
- Flammable. Keep away from fire or flame.
- When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse thoroughly with water.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away at 1-800-222-1222.
- Do not use for children less than 2 months of age or on open wounds.

Other Information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat about 40C (104F)

Directions

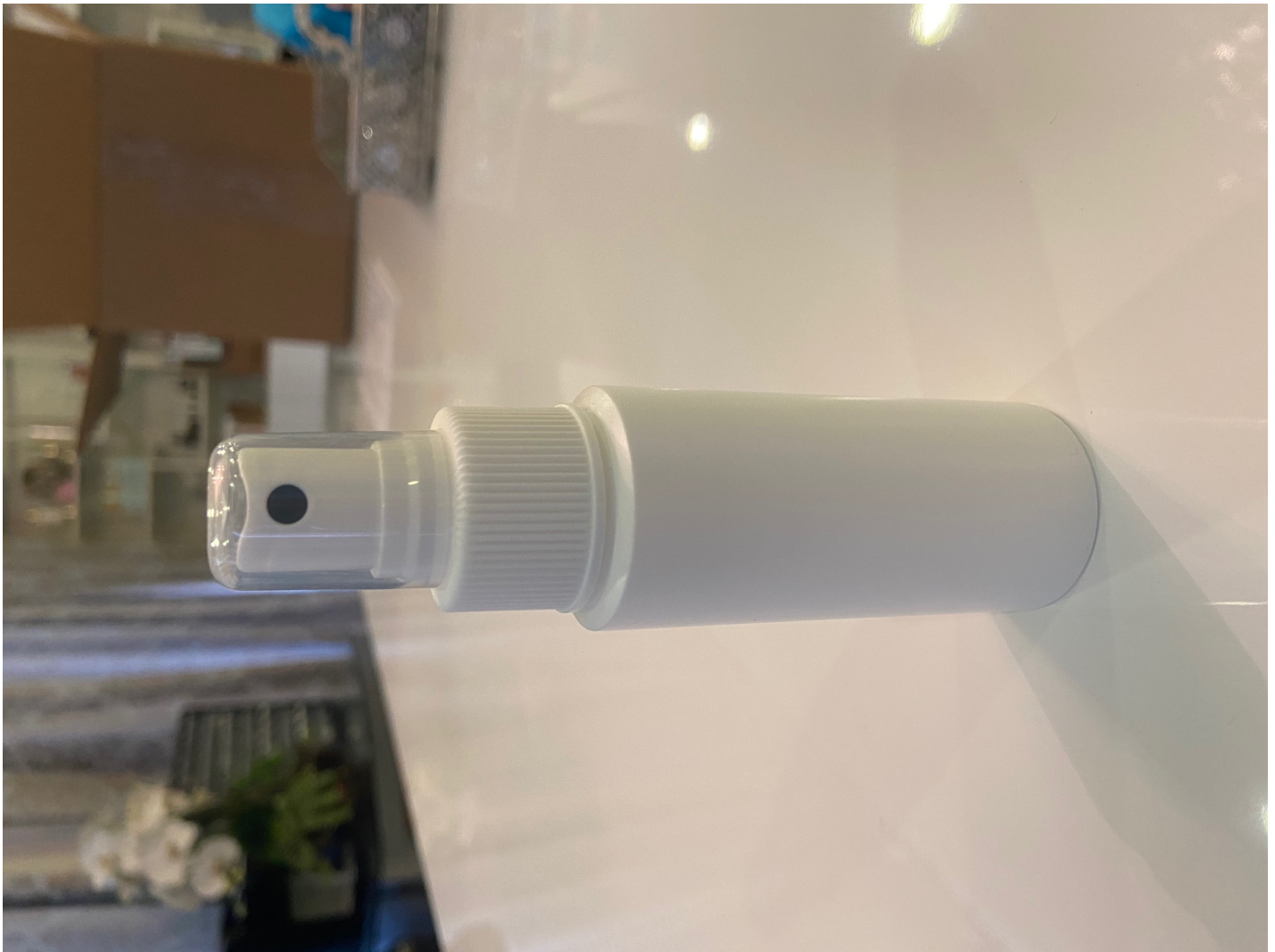
Place enough on hands to cover all surfaces. Rub hands together until dry.

Inactive Ingredients

Purified Water, Hydrogen Peroxide, Glycerin, Fragrance

Made in California, USA
Distributed by Olecea Beaute LLC
www.oleceabeaute.com





59 ml NDC: 79945-159-01

HAND SANITIZER

ethyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79945-142
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	41.3 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.012 mL in 60 mL
WATER (UNII: 059QF0KO0R)	15.58 mL in 60 mL
FRAGRANCE ORANGE ORC2000765 (UNII: GX5J7UXQ7)	0.708 mL in 60 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	2.4 mL in 60 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79945-142-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/30/2020	

Labeler - San Marino Beauty Inc. (077220394)**Registrant** - San Marino Beauty Inc. (077220394)**Establishment**

Name	Address	ID/FEI	Business Operations
San Marino Inc.		077220394	manufacture(79945-142)

Revised: 8/2020

San Marino Beauty Inc.