

**HAND SANITIZER- alcohol gel**  
**Malibu Wellness, 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.*

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**Hand Sanitizer**

**Active Ingredient(s)**

Alcohol 80% 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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**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**

Purified Water USP, Glycerin, Carbomer, Propylene Glycol, Hydrogen Peroxide, Triethanolamine.

# Package Label - Principal Display Panel

Item#	34118
Date Modified:	April 23, 2020 1:27 PM
Revision:	0



Label Material: Clear Label. Please flood with white.

Colors:

- 10222 Pantone - Purple
- 1365 Pantone - Orange
- Flexo Print White - Please flood

# HAND SANITIZER

alcohol gel

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69506-3658
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.15 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	17.435 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.15 mL in 100 mL
CARBOMER 980 (UNII: 4Q93RCW27E)	0.69 mL in 100 mL

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69506-3658-9	266 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - Malibu Wellness, Inc. (194109013)

**Registrant** - Malibu Wellness, Inc. (194109013)

## Establishment

Name	Address	ID/FEI	Business Operations
Malibu Wellness, Inc.		194109013	manufacture(69506-3658)