

JMAX HAND SANITIZER- alcohol solution

JMAX HAND SANITIZER- alcohol spray

JMAX California Co.

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.

JMax Hand Sanitizer 75% Alcohol

Information

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 & Purpose

Antimicrobial

Active Ingredient	Purpose
Ethyl Alcohol 75% v/v.....	Antimicrobial

Use

Jmax hand sanitizer gel helps 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.

Directions

- apply gel sanitizer on your palm and rub hands together covering entire hands until dry.
- supervise children under 6 years of age when using this product to avoid swallowing.

14 Oz Spray

- spray enough product to cover all surfaces
- on hands rub together until dry
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

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

14 oz Spray -

- do not puncture or incinerate. Contents under pressure

Inactive ingredients

glycerin, hydrogen peroxide, water

14 Oz -

Inactive ingredients

glycerin, sodium benzoate, trolamine, water

Package Label - Principal Display Panel

Jmax Hand Sanitizer 75% Alcohol

100 mL NDC: 78917-100-03

180 mL NDC: 78917-100-05

236 mL NDC: 78917-100-08

450 mL NDC: 78917-100-13

480 mL NDC: 78917-100-14






Antibacterial
Sanitizing
Spray

75%

Ethyl Alcohol

**KILLS 99.99% OF ILLNESS
CAUSING GERMS***

A red trapezoidal shape is shown, representing a volume measurement. The shape is wider at the bottom and tapers slightly towards the top. It is filled with a solid red color and has a thin black border. The text "5.5 fl.oz. (180 mL)" is centered within the shape in white font.

5.5 fl.oz. (180 mL)



**Antibacterial
Sanitizing
Spray**

75%
Ethyl Alcohol

Kills germs in 30 seconds
KILLS 99.99% OF ILLNESS
CAUSING GERMS*

14.0 fl.oz (450ml)



Hand Sanitizer

75% Alcohol
Antibacterial

**KILLS 99.99% OF ILLNESS
CAUSING GERMS***

Topical Soothing Gel

3 fl.oz.(100 mL)

JMAX HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78917-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78917-100-03	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:78917-100-05	180 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
3	NDC:78917-100-08	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:78917-100-13	450 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/04/2020	

Marketing Information

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

JMAX HAND SANITIZER

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78917-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78917-101-14	480 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/30/2020	

Labeler - JMAX California Co. (117139252)

Revised: 1/2021

JMAX California Co.