HAND SANITIZER- ethyl alcohol liquid
CJ Spirits LLC

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.

Active Ingredients

Alcohol 80%v/v

Do Not Use

In children less than two years of age or on open skin wounds

Warnings

For external use only. Flamable. Keep away from heat or flame

Stop Use

Stop use and ask doctor if irritation or rash occurs

Purpose

Antiseptic

Inactive Ingredients

glycerin, hydrogen peroxide, purified water USP

Instructions for use

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

Keep out of reach of children

Keep out of reach of children.

If swallowed get medical help or contact a poison control center immediately

Other information

Store between 15-30C (59=86F)

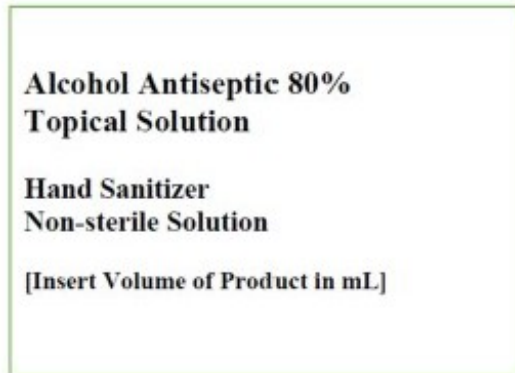Avoid freezing and excessive heat above 40C (104F)

Dosage & Administration

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

Usage

Hand sanitizer to help reduce bacteria that can cause disease. For use when soap and water are not

available

Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer
Non-sterile Solution

[Insert Volume of Product in mL]

DRUG FACTS LABEL

Drug Facts

Active ingredient[s]	Purpose
Alcohol 80% v/v...	Antiseptic

Use[s]
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.

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

Active Ingredients purpose

Alcohol 80%v/v..antiseptic

Uses

Hand sanitizer to help reduce bacteria that can cause disease. For use when soap and water are not available

Warnings

For external use only. Flamable. Keep away from heat or flame

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In children less than two years 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 doctor if irritation or rash occurs

Keep out of reach of children.

If swallowed get medical help or contact a poison control center immediately

Place enough product on your hand 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

HAND SANITIZER
ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73912-100
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
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	4.17 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0KO0R)	12.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73912-100-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	
2	NDC:73912-100-02	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	
3	NDC:73912-100-03	118.3 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	
4	NDC:73912-100-04	148 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	
5	NDC:73912-100-05	375 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	
6	NDC:73912-100-06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/24/2020	

Labeler - CJ Spirits LLC (063779302)

Registrant - CJ Spirits LLC (063779302)

Establishment

Name	Address	ID/FEI	Business Operations

| CJ Spirits LLC | | 063779302 | manufacture(73912-100) |