

HAND SANITIZER- alcohol liquid

Emergency Medical Solutions 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.

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)

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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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





HAND SANITIZER
Alcohol Antiseptic 80%
Topical Solution

Non-sterile Solution
Kills 99.99% of Germs*

4.06 FL OZ (120 ml)

Drug Facts

Active Ingredient[s] Purpose
Alcohol 80%v/v Antiseptic

Use[s]

Hand Sanitizer to help reduce bacteria potentially can cause disease. For use when soap and water not available.

Warnings

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

Do not use

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Drug Facts

Directions

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Other information

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

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

*Effective at eliminating more than 99.99% of many harmful germs and bacteria

Made in China

Imported and distributed by
Emergency Medical Solutions LLC, NY
Email: orders@ems.team



HAND SANITIZER

Alcohol Antiseptic 80% - Topical Solution

Non-sterile Solution - Kills 99.99% of Germs*

8.45 FL OZ (250ml)

Imported and distributed by Emergency
Medical Solutions LLC, NY
Email: orders@ems.team

*Effective at eliminating more than 99.99% of many harmful germs and bacteria

Made in China

Drug Facts

Active Ingredient[s] Purpose
Alcohol 80%v/v Antiseptic

Use[s] Hand Sanitizer to help reduce bacteria potentially can cause disease. For use when soap and water not available.

Warnings

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

Do not use

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- on open skin wounds

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP



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HAND SANITIZER

Alcohol Antiseptic 80% - Topical Solution

Non-sterile Solution - Kills 99.99% of Germs*

16.91 FL OZ (500 ml)

Drug Facts	
Active Ingredient(s)	Purpose
Alcohol 80%w/v	Antiseptic
Use(s)	
Hand Sanitizer to help reduce bacteria potentially can cause disease. For use when soap and water 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 15-30 °C (59-86 °F) ■ Avoid freezing and excessive heat above 40 °C (104 °F)	
Inactive ingredients: glycerin, hydrogen peroxide, purified water USP	

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HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76885-002(NDC:55467-003)
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	
GLYCERIN (UNII: PDC6A3C0OX)			1.45 mL in 100 mL	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)			0.125 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor		Imprint Code	GERMSMASH	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76885-002-06	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
2	NDC:76885-002-08	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/03/2020	
3	NDC:76885-002-11	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/03/2020	
4	NDC:76885-002-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	05/03/2020	

Labeler - Emergency Medical Solutions LLC (117478411)

Establishment			
Name	Address	ID/FEI	Business Operations
Emergency Medical Solutions LLC		117478411	label(76885-002) , relabel(76885-002)

Revised: 5/2020

Emergency Medical Solutions LLC