

HAND SANITIZER- alcohol liquid

Raff Beverage, 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.

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

Package Label - Principal Display Panel

237 mL NDC: 74610-008-08



74610-008-16

TAKE A BITE OUT OF GERMS

Non-Sterile Solution

HAND



SANITIZER

ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION

REFILL
473 mL / 16 oz.

RAFF DISTILLERIE
1615 INNES AVE
SAN FRANCISCO, CA 94124

A World Health Organization

RAFF DISTILLERIE
1615 INNES
SAN FRANCISCO,
PH: 415-610
RAFF DISTILLERIE

Drug Facts

Active ingredient(s)

Alcohol 80% v/v

Use(s) Hand Sanitizer to help reduce bacteria and viruses that cause disease. For use when soap and water are not available.

Warnings For external use only. Flammable.

Do not use

- in children less than 2 months old
- on open skin wounds

When using this product keep out of mouth. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if irritation persists or if you experience a rash.

These may be signs of a serious allergic reaction.

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.

- Supervise children under 6 years of age when using.

Other information • Store between 15-30°C (59-86°F).

- Avoid freezing and excessive heat.

Inactive ingredients glycerin, hydrogen peroxide, and fragrance.



750 mL NDC: 74610-008-75

TAKE A BITE OUT OF GERMS

HAND



TOPICAL SOLUTION SPRAY REFILL

SANITIZER

NON-STERILE SOLUTION
ALCOHOL ANTISEPTIC 80%
25.36 OZ (750ML)

A World Health Organization Approved Formula

Drug Facts	
Active ingredient[s] Alcohol 80% v/v	Purpose 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	
<ul style="list-style-type: none"> • 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.	
<ul style="list-style-type: none"> • Supervise children under 6 years of age when using this product to avoid swallowing. 	
Other information • Store between 15-30C (59-86F)	
<ul style="list-style-type: none"> • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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74610

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:746 10-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6 A3C0 OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060 AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0 KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:74610-008-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:74610-008-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74610-008-01	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:74610-008-75	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - Raff Beverage, LLC (051628773)

Establishment

Name	Address	ID/FEI	Business Operations
Raff Beverage, LLC		051628773	manufacture(74610-008)