

HAND SANITIZER- alcohol solution
Ogden's Own Distillery, 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.

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

473 mL NDC: 77863-001-16

16 oz

The
FIVE WIVES




Sanitize
HAND SANITIZER
16 oz. (355 ML)

Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution

- Not for internal consumption
Made by Ogden's Own Distillery, Ogden UT
- WHO-RECOMMENDED HANDRUB FORMULATION
 - FOR EXTERNAL USE ONLY
 - AVOID CONTACT WITH EYES
 - KEEP OUT OF THE REACH OF CHILDREN
 - USE: APPLY A PALMFUL OF ALCOHOL-BASED HANDRUB AND COVER ALL SURFACES OF THE HANDS. RUB HANDS UNTIL DRY
 - FLAMMABLE: KEEP AWAY FROM FLAME AND HEAT

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.	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



8 57519 00438 4

118 mL NDC: 77863-001-04

4 oz

The
FIVE WIVES



Sanitize
HAND SANITIZER
Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution
4 OZ. (118ML)

Trade Name	Hand Sanitizer
Active Ingredient(s)	80% Ethanol, Glycol, Hydrogen Peroxide
Net Content	4 OZ (118ML)
Directions	Apply to hands and rub thoroughly until completely dry. Do not use on face or other mucous membranes.
Warnings	For external use only. Irritating. Keep away from heat and flame.
Precautions	• Avoid contact with eyes. • Avoid contact with clothing.
Other Information	• Contains 80% alcohol. Do not use on open wounds or cuts. • Contains 2% Hydrogen Peroxide. Do not use on sensitive skin. • Contains 18% Glycol. Do not use on sensitive skin. • Contains 2% Hydrogen Peroxide. Do not use on sensitive skin.
Other Information	• Contains 80% alcohol. Do not use on open wounds or cuts. • Contains 2% Hydrogen Peroxide. Do not use on sensitive skin. • Contains 18% Glycol. Do not use on sensitive skin. • Contains 2% Hydrogen Peroxide. Do not use on sensitive skin.
Manufacturer Information	Ogden's Own Distillery, Ogden, UT

Not for internal consumption
Active ingredients: 80% Ethanol, Glycol,
Hydrogen Peroxide
Made by Ogden's Own Distillery, Ogden UT

- WHO-RECOMMENDED HANDRUB FORMULATION
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- FLAMMABLE: KEEP AWAY FROM FLAME AND HEAT



The
FIVE HUSBANDS



Sanitize
HAND SANITIZER
Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution
4 OZ. (118ML)

Trade Name	Hand Sanitizer
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18.9 L NDC: 77863-001-50

5 gallon

The
FIVE WIVES



Sanitize

HAND SANITIZER

5 GALLONS (18.93 LITERS)

Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution

237 mL NDC: 77863-001-08
8 oz

- Not for internal consumption
Made by Ogden's Own Distillery, Ogden UT
- WHO-RECOMMENDED HANDRUB FORMULATION
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 - USE: APPLY A PALMFUL OF ALCOHOL-BASED HANDRUB AND COVER ALL SURFACES OF THE HANDS. RUB HANDS UNTIL DRY
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Drug Facts	Purpose
Active ingredient(s) 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.	
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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 glycerin, hydrogen peroxide, purified water USP	



The
FIVE WIVES



Sanitize

HAND SANITIZER

8 oz.

3.79 L NDC: 77863-001-10
1 gallon

- Not for internal consumption
Active ingredients: 80% Ethanol, Glycol,
Hydrogen Peroxide
Made by Ogden's Own Distillery, Ogden UT
- WHO-RECOMMENDED HANDRUB FORMULATION
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DATE:



BATCH:

The

FIVE WIVES



Sanitize

HAND SANITIZER

128 OUNCES

1 US GALLON

Not for internal consumption

Active ingredients: 80% Ethanol, Glycol,
Hydrogen Peroxide

Made by Ogden's Own Distillery, Ogden UT

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DATE:



BATCH:

355 mL NDC: 77863-001-12

12 oz

The
FIVE WIVES



Sanitize
HAND SANITIZER
12 OZ. (355 ML)

Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution

Not for internal consumption
Made by Ogden's Own Distillery, Ogden UT

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Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% v/v.....	Antiseptic
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



59 mL NDC: 77863-001-02
2 oz

The
FIVE WIVES



Sanitize
HAND SANITIZER
2 OZ.

Not for internal consumption
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Hydrogen Peroxide
Made by Ogden's Own Distillery, Ogden UT

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The
FIVE HUSBANDS



Sanitize
HAND SANITIZER
Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution
2 OZ.

Not for internal consumption
Active ingredients: 80% Ethanol, Glycol,
Hydrogen Peroxide
Made by Ogden's Own Distillery, Ogden UT

- WHO-RECOMMENDED HANDRUB FORMULATION
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9.45 L NDC: 77863-001-25
2.5 gallon

The FIVE WIVES



Sanitize

HAND SANITIZER

2.5 GALLONS (9.46 LITERS)

Alcohol Antiseptic 80% Topical Solution
Hand Sanitizer Non-sterile Solution

Not for internal consumption
Made by Ogden's Own Distillery, Ogden UT

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Drug Facts	
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Alcohol 80% v/v	Antiseptic
Use(s)	
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP	



HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77863-200
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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:77863-200-02	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77863-200-08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77863-200-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77863-200-12	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77863-200-10	3790 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77863-200-50	1890 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
7	NDC:77863-200-04	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/12/2020	
8	NDC:77863-200-25	9460 mL in 1 JUG; Type 0: Not a Combination Product	06/23/2020	

Marketing Information

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

Labeler - Ogden's Own Distillery, Inc (012321157)

Registrant - Ogden's Own Distillery, Inc (012321157)

Establishment

Name	Address	ID/FEI	Business Operations
Ogden's Own Distillery		012321157	manufacture(77863-200)

Revised: 5/2020

Ogden's Own Distillery, Inc