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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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right

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)

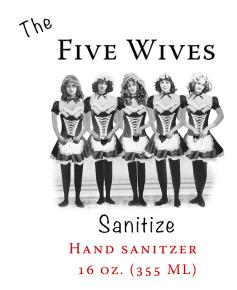
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

473 mL NDC: 77863-001-16

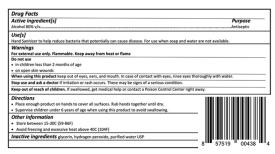
16 oz



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



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. (118 ML)



Not for internal consumption Active ingredients: 80% Ethanol, Glycol, Hydrogen Peroxide 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



The Five Husbands



Sanitize

Hand Sanitzer

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



Not for internal consumption Active ingredients: 80% Ethanol, Glycol, Hydrogen Peroxide 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

DATE:



Ватсн:

18.9 L NDC: 77863-001-50

5 gallon

The

FIVE WIVES



Sanitize

HAND SANITZER
5 GALLONS (18.93 LITERS)

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 Porcs
Active ingredient(s)
Purpose
Active ingredient(s)
Anthropic (1807)
Anthropic (18



237 mL NDC: 77863-001-08

8 oz

The FIVE WIVES



Sanitize Hand sanitzer 8 oz. Not for internal consumption

Active ingredients: 80% Ethanol, Glycol,
Hydrogen Peroxide

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

DATE:



Ватсн:

3.79 L NDC: 77863-001-10

1 gallon

The

FIVE WIVES



Sanitize

HAND SANITZER

Not for internal consumption Active ingredients: 80% Ethanol, Glycol, Hydrogen Peroxide 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

DATE:



Ватсн:

355 mL NDC: 77863-001-12

12 oz

The FIVE WIVES



Sanitize
Hand sanitzer

12 OZ. (355 ML)

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

59 mL NDC: 77863-001-02

2 oz

Tive Wives



Sanitize
Hand sanitzer
2 oz.

Five Husbands



Sanitize

Hand Sanitzer

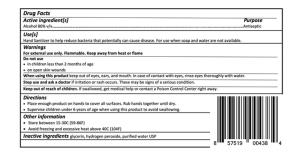
Alcohol Antileptic 80% Topical Solution
Hand Sanitzer Non-sterils Solution

9.45 L NDC: 77863-001-25

2.5 gallon

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



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

DATE: 8 57519 00434 6

Not for internal consumption
Active ingredients: 80% Ethanol, Glycol,
Hydrogen Peroxide
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



BATCH:

The

FIVE WIVES



Sanitize

HAND SANITZER
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

- 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

Active ingredient(s) Alsohol 80% y/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	
 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, rins	e eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious conditio	n,
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Cen	ter 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 inaredients glycerin, hydrogen peroxide, purified water USP	



HAND SANITIZER

alcohol solution

Product	Inform	ation
Promin	IIIIMEIII	211

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:77863-200

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (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
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

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#	Itam Cada	Package Description	Marketing Start	Marketing End	

#	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		0 12321157	manufacture(77863-200)	

Revised: 5/2020 Ogden's Own Distillery, Inc