HAND SANITIZER- alcohol liquid
HRI Holdings, 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.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin. Recommended for repeated use.

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 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, hydroxypropyl guar

Package Label - Principal Display Panel

118 mL NDC: 77463-004-01

118 mL NDC: 77463-004-06

HAND SANITIZER

Topical Liquid Solution

Alcohol Antiseptic 80% **Non-Sterile Solution**

CAUTION:
KEEP OUT OF REACH
OF CHILDREN.
Read precautions on back.

4 OZ. (118 mL)

Harris Research, Inc.
Part of the BELFOR
Franchise Group
Logan, UT 84321
435-755-0099

Best before 10/2022

Drug Facts

Active Ingredient(s) — ***Purpose***
Alcohol 80% v/v ..... Antiseptic

Use(s)
Hand sanitizer to help reduce bacteria on the skin. Recommended for repeated use.

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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, sterile water

473 mL NDC: 77463-004-07

HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77463-004
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)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77463-004-01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	

2	NDC:77463-004-06	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	
3	NDC:77463-004-07	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/15/2020	

Labeler - HRI Holdings, Inc. (025501919)

Establishment

Name	Address	ID/FEI	Business Operations
HRI Holdings, Inc.		025501919	manufacture(77463-004)

Revised: 10/2020 HRI Holdings, Inc.