

## **HELIX HAND SANITIZER- ethanol hand sanitizer gel**

**Helix Spirits 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.*

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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**

<b>DRUG FACTS</b>	
<b>Active Ingredient</b> Ethanol 80% v/v .....	<b>Purpose</b> Antimicrobial
<b>Uses</b> Topical hand sanitizer to reduce bacteria when soap and water are not available.	
<b>Warnings</b> For external use only. Flamable. Keep away from fire or flame. Keep out of reach of children.	
<b>Directions</b> Put enough on hands to cover them completely and rub until dry.	
<b>Inactive ingredients</b> Purified water, hydrogen peroxide, glycerin	

Manufactured in Iceland:  
Hedinsgata 2  
104 Reykjavik



**HAND  
SANITIZER**  
*by*  
**HELIX7**  
V O D K A

# HAND SANITIZER

Alcohol-based Hand Sanitizer

80 % Alcohol

500 ml

**EXTERNAL USE ONLY**

**DO NOT DRINK**

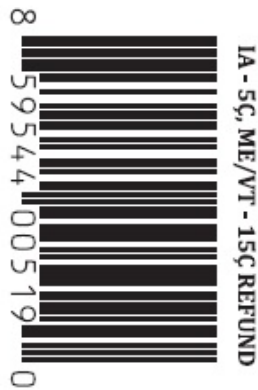
**Direction of use:** Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry  
**Avoid contact with eyes** \_\_\_\_\_

**KEEP OUT OF THE REACH OF CHILDREN**

**WHO-recommended handrub formulation**  
**Composition:** Ethanol, glycerol and hydrogen peroxide.  
**Flammable:** Keep away from flame and heat.

Helix Spirits LLC

www.wlspirits.com



## HELIX HAND SANITIZER

ethanol hand sanitizer gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77732-001
<b>Route of Administration</b>	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: 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:77732-001-50	500 mL in 1 BOTTLE, PLASTIC; 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	03/01/2020	

**Labeler** - Helix Spirits LLC (080931484)**Registrant** - Helix Spirits LLC (080931484)**Establishment**

Name	Address	ID/FEI	Business Operations
Eldfjallabrukk ehf		500772965	manufacture(77732-001)

Revised: 5/2020

Helix Spirits LLC