

## **HAND SANITIZER- alcohol liquid**

**Kem Krest**

*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:

- 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.
- Glycerol (1.45% v/v).
- Hydrogen peroxide (0.125% v/v).
- 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**

- on 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**



# HAND SANITIZER



**Alcohol Antiseptic 80%**  
**Topical Solution**  
**Non-sterile solution**  
**NDC: 74242-005-02**

**1 U.S. GALLON**  
**(3.785 L)**

## Drug Facts

Active Ingredient[s]	Purpose
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**Inactive ingredients** glycerin, hydrogen peroxide, purified water USP

**Manufactured by:** Kem Krest

12785 Emerson Drive, Brighton, MI 48116 • (248) 486-3800

In case of a medical emergency using this product, call (800) 704-1559.

KK PN: 130047

## FRONT PANEL LABEL

 Melissa Tigner - Graphic Designer (248) 587-1143 • mtigner@kemkrest.com	NAME: Kem Krest - Hand Sanitizer - 1 gallon DATE: 4-3-2020 v9 DIE SIZE: 6"w x 5"h CR: 0.125" COLORS: see right COATING: <input type="checkbox"/> UV <input checked="" type="checkbox"/> Laminate <input type="checkbox"/> First Draft <input checked="" type="checkbox"/> Revision	 Black
	NOTE FOR LABEL PRINTER/SUPPLIER: Please verify the bar code scans correctly.	

3.785L NDC: 74242-005-02

## HAND SANITIZER

alcohol liquid

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:74242-005

<b>Route of Administration</b>		TOPICAL		
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	80 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
GLYCERIN (UNII: PDC6A3C0OX)		1.45 mL in 100 mL		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)		0.125 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:74242-005-02	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final		part333A	03/30/2020	

**Labeler** - Kem Krest (933954179)

**Registrant** - Kem Krest (933954179)

Establishment			
Name	Address	ID/FEI	Business Operations
Kem Krest		933954179	manufacture(74242-005)