# HAND SANITIZER- alcohol spray KB HPS

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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#### **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

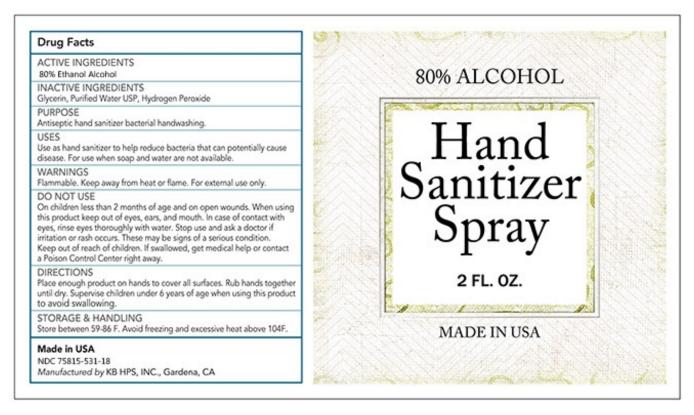
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

59 mL NDC: 75815-531-18

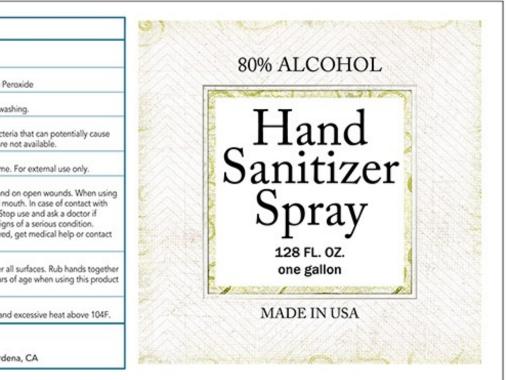


118 ml NDC 75815-531-20

#### **Drug Facts** ACTIVE INGREDIENTS 80% ALCOHOL 80% Ethanol Alcohol INACTIVE INGREDIENTS Glycerin, Purified Water USP, Hydrogen Peroxide PURPOSE Antiseptic hand sanitizer bacterial handwashing. Hand Sanitizer Use as hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available. WARNINGS Flammable. Keep away from heat or flame. For external use only. DO NOT USE On children less than 2 months of age and on open 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. DIRECTIONS 4 FL. OZ. 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. STORAGE & HANDLING Store between 59-86 F. Avoid freezing and excessive heat above 104F. MADE IN USA Made in USA NDC 75815-531-20

#### 3785 ml NDC 75815-531-22

Manufactured by KB HPS, INC., Gardena, CA



# Drug Facts

ACTIVE INGREDIENTS

80% Ethanol Alcohol

INACTIVE INGREDIENTS

Glycerin, Purified Water USP, Hydrogen Peroxide

PURPOSE

Antiseptic hand sanitizer bacterial handwashing.

USES

Use as hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from heat or flame. For external use only.

DO NOT USE

On children less than 2 months of age and on open 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.

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.

STORAGE & HANDLING

Store between 59-86 F. Avoid freezing and excessive heat above 104F.

Made in USA

NDC 75815-531-22

Manufactured by KB HPS, INC., Gardena, CA

## HAND SANITIZER

alcohol spray

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75815-531

# Active Ingredient/Active Moiety

	Ingredient Name	<b>Basis of Strength</b>	Strength
l	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

# **Inactive Ingredients**

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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)		

## **Packaging**

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#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:75815-531- 18	30000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/11/2020		
2	NDC:75815-531- 20	30000 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/11/2020		
3	NDC:75815-531- 22	30000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020		

# **Marketing Information**

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/11/2020	

# **Labeler -** KB HPS (080303528)

Establishment				
Name	Address	ID/FEI	Business Operations	
KB HPS		080303528	manufacture (758 15-531)	

Revised: 5/2020 KB HPS