

KAS SPIRITS HAND SANITIZER- kas spirits hand sanitizer liquid
KAS 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.

 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)

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Alcohol 80% v/v. Purpose: Antiseptic

Drug Facts	
Active ingredient(s)	Purpose
Alcohol 80% v/v.....	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	
<ul style="list-style-type: none"> • 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.	
Directions	
<ul style="list-style-type: none"> • 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	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients glycerin, hydrogen peroxide, purified water USP	

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 MANUFACTURED BY
 KAS SPIRITS
 MAHOPAC, NY 10541
 (845) 750-6000

Purpose

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Antiseptic

Use(s)

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Package Label - Principal Display Panel

KAZAP

Alcohol Antiseptic 80%

Topical Solution

Hand Sanitizer Non-sterile Solution

2 fl. oz. (59ml) NDC 74636-001-01

Drug Facts

Active ingredient[s] Purpose

Alcohol 80% v/v.....Antiseptic

Use[s]

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KAS SPIRITS HAND SANITIZER

kas spirits hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74636-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	47.32 mL in 59.15 mL

Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.0739 mL in 59.15 mL
WATER (UNII: 059QF0K00R)	10.89 mL in 59.15 mL
GLYCEROL FORMAL (UNII: 3L7GR2604E)	0.866 mL in 59.15 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74636-0001-1	59.15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2020	

2	NDC:74636-0001-2	354.88 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2020	
3	NDC:74636-0001-3	1892.7 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2020	
4	NDC:74636-0001-4	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2020	
5	NDC:74636-0001-5	3785.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2020	
6	NDC:74636-0001-6	177.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2020	
7	NDC:74636-0001-7	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/04/2020	

Labeler - KAS SPIRITS LLC (085186376)

Establishment

Name	Address	ID/FEI	Business Operations
KAS SPIRITS LLC		085186376	manufacture(74636-0001)

Revised: 6/2020

KAS SPIRITS LLC