

HAND SANITIZER- alcohol liquid
Stark 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.

Hand Sanitizer

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.

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.

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



Alcohol Antiseptic 80%
Topical Solution

Hand Sanitizer

Non-sterile Solution WHO Formula 1

UN1987

Alcohol, n.o.s., Class 3, PG II

Lot B4 4/24/20 55 Gallons(208 Liters)

1260 Lincoln Ave #1100, Pasadena, CA 91103
TEL: (626)798-1377 NCD-76858-000-04

Drug Use	Purpose
Active ingredient[s] 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 <ul style="list-style-type: none">• Do not use in children less than 2 months of age• Do not use 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 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	





Alcohol Antiseptic
80% Topical Solution

Hand Sanitizer

Non-sterile Solution WHO Formula 1



DOT UN1987

Alcohol, n.o.s.,
Class 3, PG II

Lot B2 4/24/20

5 Gallon(18.9L)

1260 Lincoln Ave #1100, Pasadena, CA 91103
TEL: (626)798-1377 NCD-76858-000-03

<i>Active ingredient[s]</i>	<i>Purpose</i>
Alcohol 80% v/v	Antiseptic
<i>Use[s]</i> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<i>Warnings</i> For external use only. Flammable. Keep away from heat or flame <ul style="list-style-type: none"> • Do not use in children less than 2 months of age • Do not use 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.	
<i>Directions</i> <ul style="list-style-type: none"> •Place enough product on hands to cover all surfaces. Rub together until dry. •Supervise children under 6 years of age when using this product to avoid swallowing. 	
<i>Other information</i> <ul style="list-style-type: none"> •Store between 15-30C (59-86F) •Avoid freezing and excessive heat above 40C (104F) 	
<i>Inactive ingredients</i> glycerin, hydrogen peroxide, purified water USP	



Alcohol Antiseptic
80% Topical Solution

Hand Sanitizer

Non-sterile Solution WHO Formula 1



DOT UN1987

Alcohol, n.o.s.,
Class 3, PG II

Lot B4 4/24/20

Half Gallon(1.89L)

1260 Lincoln Ave #1100, Pasadena, CA 91103
TEL: (626)798-1377 NCD-76858-000-02

<i>Active ingredient[s]</i>	<i>Purpose</i>
Alcohol 80% v/v	Antiseptic
<i>Use[s]</i> Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
<i>Warnings</i> For external use only. Flammable. Keep away from heat or flame <ul style="list-style-type: none"> • Do not use in children less than 2 months of age • Do not use 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.	
<i>Directions</i> <ul style="list-style-type: none"> •Place enough product on hands to cover all surfaces. Rub together until dry. •Supervise children under 6 years of age when using this product to avoid swallowing. 	
<i>Other information</i> <ul style="list-style-type: none"> •Store between 15-30C (59-86F) •Avoid freezing and excessive heat above 40C (104F) 	
<i>Inactive ingredients</i> glycerin, hydrogen peroxide, purified water USP	



Alcohol Antiseptic
80% Topical Solution

Hand Sanitizer

Non-sterile Solution WHO Formula 1



DOT UN1987

Alcohol, n.o.s.,
Class 3, PG II

Lot B4 4/24/20 1 Quart(946mL)

1260 Lincoln Ave #1100, Pasadena, CA 91103
TEL: (626)798-1377 NCD-76858-000-01

Active ingredient[s] Alcohol 80% v/v	Purpose 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 <ul style="list-style-type: none"> Do not use in children less than 2 months of age Do not use 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 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	

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76858-000
Route of Administration	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: BBX060 AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76858-000-00	964 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	

2	NDC:76858-000-01	1892.71 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76858-000-02	18927 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76858-000-03	208198 mL in 1 DRUM; 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	03/30/2020	

Labeler - Stark Spirits LLC (047945646)

Registrant - Stark Spirits LLC (047945646)

Establishment

Name	Address	ID/FEI	Business Operations
Stark Spirits LLC		047945646	manufacture(76858-000)

Revised: 4/2020

Stark Spirits LLC