

**HAND SANITIZER- alcohol gel**  
**HAND SANITIZER- alcohol liquid**  
**Horizon Tool Inc.**

*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.

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

236 mL NDC: 74683-2000-1

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70% v/v.....	Antimicrobial
<b>Warnings</b>	
Flammable. Keep away from fire or flame.	
When using this product do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.	
Stop use and seek medical attention if irritation or rash appears or persists.	
Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control immediately.	
For external use only. Do not ingest.	
Other info • Store below 110°F (43°C)	
Inactive ingredients Glycerin, Hydroxypropyl Cellulose, Purified Water USP	

Item# 2258

**ALLSHIELD**  
HAND  
SANITIZER  
70% ALCOHOL

PROUDLY  
MADE IN THE USA

**EXCEEDS THE CDCs RECOMMENDED  
ALCOHOL STRENGTH**

8 FL OZ (236 ML)

**Directions for use:**  
Apply product to your hands and rub together vigorously.  
Allow them to air dry.  
Avoid wiping your hands dry.

Distributed by Horizon Tool, Incorporated  
7918 Industrial Village Road.  
Greensboro, NC 27409  
Made in USA      EXP 09/2022

0 47084 02258 0  
This product can damage some surfaces.

473 mL NDC: 74683-1000-2

**Drug Facts**

Active ingredient	Purpose
Ethyl alcohol 70% v/v.....	Antimicrobial

**Warnings**

**Flammable. Keep away from fire or flame**

**When using this product** do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.

**Stop use and seek medical attention** if irritation or rash appears or persists.

**Keep out of the reach of children.**

If swallowed, seek medical assistance or contact your local Poison Control immediately.

**For external use only. Do not ingest.**

**Other info** • Store below 110°F (43°C)

**Inactive ingredients** Glycerin, Hydroxypropyl Cellulose, Purified Water USP



This product can damage some surfaces.



**ALLSHIELD**  
HAND  
**SANITIZER**  
70% ALCOHOL

PROUDLY  
MADE IN THE USA



**EXCEEDS THE CDCs RECOMMENDED  
ALCOHOL STRENGTH**

16 FL OZ (473 ML)

Item# 22516



**Directions for use:**

Apply product to your hands and rub together vigorously.

Allow them to air dry.

Avoid wiping your hands dry.

Distributed by Horizon Tool, Incorporated  
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Greensboro, NC 27409

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EXP 09/2022

946.35 mL NDC: 74683-1000-3



**ALLSHIELD**  
HAND  
**SANITIZER**  
70% ALCOHOL

PROUDLY  
MADE IN THE USA



**EXCEEDS THE CDCs RECOMMENDED  
ALCOHOL STRENGTH**

32 FL. OZ. (946.35 ML)

946.35 mL NDC: 74683-1000-3



Item# 22532

**Drug Facts**

<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70% v/v.....	Antimicrobial

**Warnings**

**Flammable. Keep away from fire or flame.**

**When using this product** do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.

**Stop use and seek medical attention** if irritation or rash appears or persists.

**Keep out of the reach of children.** If swallowed, seek medical assistance or contact your local Poison Control immediately.

**For external use only. Do not ingest.**

**Other info** • Store below 110°F (43°C)

**Inactive ingredients** Glycerin, Hydroxypropyl Cellulose, Purified Water USP

**Directions for use:**

Apply product to your hands and rub together vigorously.

Allow them to air dry.

Avoid wiping your hands dry.

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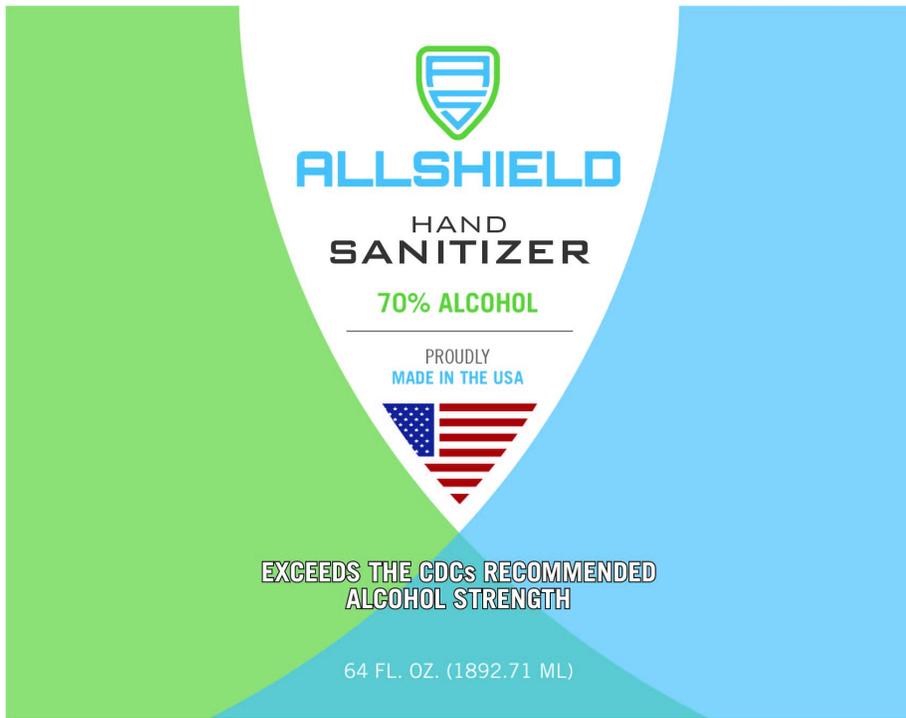
Made in USA

This product can damage certain surfaces.

EXP 09/2022



1892.71 mL NDC: 74683-1000-4



3785.41 mL NDC: 74683-1000-5



Item# 22564

**Directions for use:**  
Apply product to your hands and rub together vigorously.  
Allow them to air dry.  
Avoid wiping your hands dry.

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70% v/v.....	Antimicrobial
<b>Warnings</b>	
<b>Flammable. Keep away from fire or flame.</b>	
When using this product do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.	
Stop use and seek medical attention if irritation or rash appears or persists.	
Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control immediately.	
For external use only. Do not ingest.	
<b>Other info</b> • Store below 110°F (43°C)	
<b>Inactive ingredients</b> Glycerin, Hydroxypropyl Cellulose, Purified Water USP	

\*This product can damage certain surfaces.

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473 mL NDC: 74683-2000-1



Item# 22528

**Directions for use:**  
Apply product to your hands and rub together vigorously.  
Allow them to air dry.  
Avoid wiping your hands dry.

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 70% v/v.....	Antimicrobial
<b>Warnings</b>	
<b>Flammable. Keep away from fire or flame.</b>	
When using this product do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.	
Stop use and seek medical attention if irritation or rash appears or persists.	
Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control immediately.	
For external use only. Do not ingest.	
<b>Other info</b> • Store below 110°F (43°C)	
<b>Inactive ingredients</b> Glycerin, Hydroxypropyl Cellulose, Purified Water USP	

\*This product can damage certain surfaces.

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# ALLSHIELD

## SPRAY SANITIZER

### 80% ALCOHOL

#### Directions for use:

Apply product to your hands  
and rub together vigorously.

Allow them to air dry.

Avoid wiping your hands dry.

If using on a hard  
surface\*, begin by testing  
a small inconspicuous area

If pleased, with the results  
spray and wipe dry or let air dry

PROUDLY  
MADE IN THE USA



**EXCEEDS THE CDCs RECOMMENDED  
ALCOHOL STRENGTH**

16 FL OZ (473 ML)

473 mL NDC: 74683-2000-1

Item# 22616

**Drug Facts**

<i>Active ingredient</i>	<i>Purpose</i>
Ethyl alcohol 80% v/v.....	Antimicrobial

**Warnings**

**Flammable. Keep away from fire or flame.**

**When using this product** do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.

**Stop use and seek medical attention** if irritation or rash appears or persists.

**Keep out of the reach of children.** If swallowed, seek medical assistance or contact your local Poison Control immediately.

**For external use only. Do not ingest.**

**Other info** • Store below 110°F (43°C)

**Inactive ingredients** Glycerin, Hydrogen Peroxide, Purified Water USP

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Greensboro, NC 27409

EXP 09/2022

Made in USA



\* Product can damage some surfaces

946.35 mL NDC: 74683-2000-2



**ALLSHIELD**

SPRAY  
**SANITIZER**

**80% ALCOHOL**

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PROUDLY  
**MADE IN THE USA**



**EXCEEDS THE CDCs RECOMMENDED  
ALCOHOL STRENGTH**

32 FL. OZ. (946.35 ML)

946.35 mL NDC: 74683-2000-2



Item# 22632

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Isopropyl alcohol 80% v/v.....	Antimicrobial
<b>Warnings</b>	
<b>Flammable. Keep away from fire or flame</b>	
<b>When using this product</b> do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.	
<b>Stop use and seek medical attention</b> if irritation or rash appears and lasts.	
<b>Keep out of the reach of children.</b>	
<b>For external use only. Do not ingest.</b> If swallowed, seek medical assistance or contact your local Poison Control immediately.	
<b>Other info</b> • Store below 110°F (43°C)	
<b>Inactive ingredients</b> Water (Aqua)	

**Directions for use:**

Apply product to your hands.  
 Rub them together vigorously.  
 Allow them to air dry.  
 Avoid wiping your hands dry.  
 If using on a hard surface\*, begin by testing a small inconspicuous area.  
 If pleased, with the results, spray and wipe dry or let air dry.

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 Made in USA

\* This product can damage certain surfaces.



EXP 09/2022

1892.71 mL NDC: 74683-2000-3



Item# 22664

**Directions for use:**

Apply product to your hands and rub together vigorously.  
 Allow them to air dry.  
 Avoid wiping your hands dry.  
 If using on a hard surface\*, begin by testing on a small inconspicuous area.  
 If pleased, with the results, spray and wipe dry or let air dry.

<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Ethyl alcohol 80% v/v.....	Antimicrobial
<b>Warnings</b>	
<b>Flammable. Keep away from fire or flame.</b>	
<b>When using this product</b> do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.	
<b>Stop use and seek medical attention</b> if irritation or rash appears or persists.	
<b>Keep out of the reach of children.</b> If swallowed, seek medical assistance or contact your local Poison Control immediately.	
<b>For external use only. Do not ingest.</b>	
<b>Other info</b> • Store below 110°F (43°C)	
<b>Inactive ingredients</b> Glycerin, Hydrogen Peroxide, Purified Water USP	

\*This product can damage certain surfaces.

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Distributed by Horizon Tool, Incorporated  
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3785.41 mL NDC: 74683-2000-4

**Directions for use:**  
 Apply product to your hands and rub together vigorously.  
 Allow them to air dry.  
 Avoid wiping your hands dry.  
 If using on a hard surface\*, begin by testing on a small inconspicuous area.  
 If pleased, with the results, spray and wipe dry or let air dry.

Drug Facts	
Active ingredient	Purpose
Ethyl alcohol 80% v/v	Antimicrobial
<b>Warnings</b>	
<b>Flammable.</b> Keep away from fire or flame.	
When using this product do not use in or near the eyes, ears and mouth. In case of contact, rinse eyes thoroughly with water.	
Stop use and seek medical attention if irritation or rash appears or persists.	
Keep out of the reach of children. If swallowed, seek medical assistance or contact your local Poison Control immediately.	
For external use only. Do not ingest.	
Other info • Store below 110°F (43°C)	
Inactive ingredients: Glycerin, Hydrogen Peroxide, Purified Water USP	

\*This product can damage certain surfaces. EXP 09/2022  
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 Greensboro, NC 27409  
 Made in USA



ALLSHIELD  
 SPRAY  
 SANITIZER

80% ALCOHOL

PROUDLY  
 MADE IN THE USA



EXCEEDS THE CDCs RECOMMENDED  
 ALCOHOL STRENGTH

1 GAL. (3785.41 ML)

## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74683-1000
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C00X)	1.45 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74683-1000-1	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
2	NDC:74683-1000-2	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
3	NDC:74683-1000-3	946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
4	NDC:74683-1000-4	1892.71 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
5	NDC:74683-1000-5	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

## HAND SANITIZER

alcohol liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74683-2000
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74683-2000-1	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
2	NDC:74683-2000-2	946.35 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
3	NDC:74683-2000-3	1892.71 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	
4	NDC:74683-2000-4	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/24/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

**Labeler** - Horizon Tool Inc. (602012460)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Surry Chemicals, Inc.		083630285	manufacture(74683-1000, 74683-2000)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Horizon Tool Inc.		602012460	repack(74683-2000, 74683-1000)

Revised: 4/2020

Horizon Tool Inc.