

**SANITECH-A2- alcohol gel**  
**S4 Water Sales and Service, 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.*

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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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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, hydroxypropyl cellulose, purified water USP

## Package Label - Principal Display Panel

The image shows the principal display panel of a Sanitech-A2 hand sanitizer package. The panel is white with black text and a blue logo. On the left, there is a logo with a blue 'S' and '4' inside a square, with 'WATER' written below it. To the right of the logo is the manufacturer's address: 160 Vanderbilt Court, Bowling Green, KY 42103, Phone (270) 781-0670. Below this is a paragraph of text explaining that the product is manufactured according to a temporary policy for alcohol-based hand sanitizer products during the COVID-19 public health emergency. It lists the ingredients: Alcohol (ethanol) 80% v/v, Glycerol 1.45% v/v, and Hydrogen peroxide 0.125% v/v. It also states that the product is sterile and that the firm does not add other active or inactive ingredients. In the center, the product name 'Sanitech-A2' is prominently displayed in a large, bold, black font. Below the name, it says 'Alcohol Antiseptic 80% Topical Solution Antiseptic Hand Rub Gel Non-Sterile Solution 236 mls NDC 76643-2255-8'. On the right side, there is a section titled 'Drug Facts' which includes 'Active ingredient(s): Alcohol 80% v/v', 'Purpose: Antiseptic', 'Use(s): Health care personnel hand rub to help reduce bacteria that potentially can cause disease', '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 wounds.', 'Directions: Rub 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.', and 'Other information: Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F)'. At the bottom right, it lists 'Inactive ingredients: glycerin, hydrogen peroxide, hydroxypropyl cellulose purified water USP'.

**S<sup>4</sup>**  
WATER

160 Vanderbilt Court  
Bowling Green, KY 42103  
Phone (270) 781-0670

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](#).

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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.

# Sanitech-A2

Alcohol Antiseptic 80%  
Topical Solution  
Antiseptic Hand Rub Gel  
Non-Sterile Solution  
236 mls  
NDC 76643-2255-8

**Drug Facts**

Active ingredient(s)	Purpose
Alcohol 80% v/v	Antiseptic

**Use(s)**  
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

**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 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. There 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**  
-Rub 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, hydroxypropyl cellulose purified water USP



160 Vanderbilt Court  
Bowling Green, KY 42103  
Phone (270) 781-0670

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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.

# Sanitech-A2

Alcohol Antiseptic 80%  
Topical Solution  
Antiseptic Hand Rub Gel  
Non-Sterile Solution  
3,785 mls  
NDC 76643-2255-3



**D.O.T Shipping**

**UN1170, Flammable Liquid, n.o.s., (Ethanol), 3, PGI**

**NET WT. 7.2 LBS.**

#### Drug Facts

Active Ingredient(s)	Purpose
Alcohol 80% v/v	Antiseptic

#### Uses

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

#### 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 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.

#### Other information

- Store between 15-30C (59-86F)

- Avoid freezing and excessive heat above 40C (103F)

Inactive ingredients glycerin, hydrogen peroxide, hydroxypropyl

cellulose, purified water USP



160 Vanderbilt Court  
Bowling Green, KY 42103  
Phone (270) 781-0670

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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.

# Sanitech-A2

Alcohol Antiseptic 80%  
Topical Solution  
Antiseptic Hand Rub Gel  
Non-Sterile Solution  
1,836 mls  
NDC 76643-2255-1



*D.O.T Shipping*  
*UN1170, Flammable Liquid, n.o.s., (Ethanol), 3, PGII*

**NET WT. 3.6 LBS.**

#### Drug Facts

Active Ingredient(s)	Purpose
Alcohol 80% v/v	Antiseptic

**Uses(s)**  
Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

**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 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. There 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, hydroxypropyl cellulose, purified water USP

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mL NDC: 00000-000-00

## SANITECH-A2

alcohol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76643-2255
<b>Route of Administration</b>	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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	1.1 mL in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76643-2255-1	1836 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76643-2255-8	236 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76643-2255-3	3785 mL in 1 JUG; 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** - S4 Water Sales and Service, LLC (930430413)

**Establishment**

Name	Address	ID/FEI	Business Operations
S4 Water Sales and Service, LLC		930430413	manufacture(76643-2255)

Revised: 4/2020

S4 Water Sales and Service, LLC