

SAWC HAND SANITIZER- 80% alcohol hand sanitizer liquid
Still Austin Whiskey Co.

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)

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

STILL AUSTIN HAND SANITIZER NON-STERILE SOLUTION	This hand sanitizer will not cure or prevent infection relative to COVID-19/CoronaVirus																																
	<table border="1"><thead><tr><th>DRUG FACTS</th><th><i>Active Ingredient</i></th><th><i>Purpose</i></th></tr></thead><tbody><tr><td><i>Use(s)</i></td><td>Alcohol 80% v/v</td><td>Antiseptic</td></tr><tr><td colspan="3">Hand sanitizer to help reduce bacteria that potential can cause disease. For use when soap and water are not available.</td></tr><tr><td><i>Warnings</i></td><td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td></tr><tr><td><i>Do Not Use</i></td><td colspan="2">- In children less than 2 months of age - on open skin wounds</td></tr><tr><td colspan="3">When using this product keep out of eyes, ears, & mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td></tr><tr><td colspan="3">Stop use & ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</td></tr><tr><td colspan="3">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="3"><i>Directions:</i> Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years in age when using this product to avoid swallowing.</td></tr><tr><td colspan="3"><i>Other Information:</i> Store between 59-86F (15-30C) Avoid freezing & excessive heat above 104F (40C)</td></tr><tr><td colspan="3"><i>Inactive Ingredients</i> glycerin, hydrogen peroxide, purified water USP</td></tr></tbody></table>	DRUG FACTS	<i>Active Ingredient</i>	<i>Purpose</i>	<i>Use(s)</i>	Alcohol 80% v/v	Antiseptic	Hand sanitizer to help reduce bacteria that potential 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.		<i>Do Not Use</i>	- In children less than 2 months of age - on open skin wounds		When using this product keep out of eyes, ears, & mouth. In case of contact with eyes, rinse eyes thoroughly with water.			Stop use & 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> Place enough product on hands to cover all surfaces. Rub hands together until dry. Supervise children under 6 years in age when using this product to avoid swallowing.			<i>Other Information:</i> Store between 59-86F (15-30C) Avoid freezing & excessive heat above 104F (40C)			<i>Inactive Ingredients</i> glycerin, hydrogen peroxide, purified water USP	
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ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION (NOT FOR CONSUMPTION)	16 FL.OZ (473 ml)	stillaustin.com (512) 276-2700																															
		Produced on																															

STILL AUSTIN HAND SANITIZER NON-STERILE SOLUTION

**ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION
(NOT FOR CONSUMPTION)**

**6.6
FL.OZ
(195 ml)**

195 mL NDC: 74365-0001-1
473 mL NDC: 75365-0001-2
3785 ml NDC: 74365-0001-4
208198 ml NDC: 74365-0001-5

This hand sanitizer will not cure or prevent infection relative to COVID-19/Coronavirus

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

Hand sanitizer to help reduce bacteria that potential can cause disease. For use when soap and water are not available.

Warnings

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Do Not Use

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Other Information: Store between 59-86F (15-30C)

Avoid freezing & excessive heat above 104F (40C)

Inactive Ingredients glycerin, hydrogen peroxide, purified water USP

stillaustin.com
(512) 276-2700

Produced on

STILL AUSTIN HAND SANITIZER NON-STERILE SOLUTION

**ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION
(NOT FOR CONSUMPTION)**

**55
Gallons**
(208.2 L)

Produced on

stillaustin.com
(512) 276-2700



This hand sanitizer will not cure or prevent infection relative to COVID-19/CoronaVirus

DRUG FACTS

Active Ingredient
Alcohol 80% v/v

Purpose
Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that potential can cause disease. For use when soap and water are not available.

Warnings

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Inactive Ingredients glycerin, hydrogen peroxide, purified water USP

STILL AUSTIN HAND SANITIZER NON-STERILE SOLUTION

**ALCOHOL ANTISEPTIC 80%
TOPICAL SOLUTION
(NOT FOR CONSUMPTION)**

**128
FL.OZ
(3,785 ml)**

**This hand sanitizer will not cure or prevent
infection relative to COVID-19/CoronaVirus**

stillaustin.com

DRUG FACTS

Active Ingredient
Alcohol 80% v/v

Purpose
Antiseptic

Use(s)

Hand sanitizer to help reduce bacteria that potential can cause disease. For use when soap and water are not available.

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Inactive Ingredients glycerin, hydrogen peroxide, purified water USP

SAWC HAND SANITIZER

80% alcohol hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74365-0001
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
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74365-0001-1	195 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/07/2020	
2	NDC:74365-0001-4	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:74365-0001-5	208198 mL in 1 DRUM; Type 0: Not a Combination Product	04/07/2020	
4	NDC:74365-0001-2	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:74365-0001-3	18927 mL in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
6	NDC:74365-0001-6	1021950 mL in 1 TANK; 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 - Still Austin Whiskey Co. (080154294)

Establishment

Name	Address	ID/FEI	Business Operations
Still Austin Distillery LLC		080154294	manufacture(74365-0001)

Revised: 5/2020

Still Austin Whiskey Co.