

**WHO RECOMMENDED HAND RUB- alcohol liquid
BRENNTAG SOUTHWEST, 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.

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

WHO RECOMMENDED HAND RUB

Danger

Hazard statement

Highly flammable liquid and vapor. Causes serious eye irritation.

Precautionary statement

Prevention

Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wash thoroughly after handling. Wear protective gloves/eye protection/face protection.

Response

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. In case of fire: Use appropriate media to extinguish.

Storage

Store in a well-ventilated place. Keep cool.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.



Product Code
910342



Clock #: .

Lot Number



Container # 1
Deposit: \$50.00
+MDRM

Supplemental information

Static accumulating flammable liquid can become electrostatically charged even in bonded and grounded equipment. Sparks may ignite liquid and vapor. May cause flash fire or explosion.

2.11% of the mixture consists of component(s) of unknown acute oral toxicity. 70.1% of the mixture consists of component(s) of unknown acute dermal toxicity. 99.82% of the mixture consists of component(s) of unknown acute inhalation toxicity.

Usage: Keep container tightly closed. Closures must be retained and tight for returning. Flammables and Combustibles: Ground and bond to certified grounding system, and use spark proof tools.

Empty containers: Do not use container for any other purpose. Containers retain hazardous materials; Follow all safety requirements as if full. Do not cut, braze, or weld on or near this container.

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. Additional information is given in the Safety Data Sheet.

California SCAQMD Rule 443.1 VOCs:

VOC: 78.11%

California Proposition 65

WARNING: This product can expose you to ACETALDEHYDE, which is known to the State of California to cause cancer, and METHANOL, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Alcohol Antiseptic 80% Topical Solution

Hand Sanitizer Non-sterile Solution

DRUG FACTS LABEL

Drug Facts	Purpose
Active ingredient(s) Isopropanol 70% Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	Antiseptic
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	
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	



HEALTH	2
FLAMMABILITY	3
REACTIVITY	0
PERSONAL PROTECTION	

Net Wt. 390.00 LB 176.90 KG

Read and understand the Safety Data Sheet for this product before handling.



Brenntag Southwest, Inc.
610 Fisher Road
Longview, TX 75604
903-759-7151
800-424-9300 CHEMTREC

Contents made in: USA

UN1170

ETHANOL SOLUTIONS; 3;
PGII

- 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

000 mL NDC: 00000-

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Hand Sanitizer Non-sterile Solution

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FLAMMABILITY	3
REACTIVITY	0
PERSONAL PROTECTION	0

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Contents made in: USA

UN1170

ETHANOL SOLUTIONS; 3;
PGII

000-00

WHO RECOMMENDED HAND RUB

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68812-4934
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: 059QF0K0OR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68812-4934			

1	NDC:68812-4934-2	208198 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:68812-4934-1	1040988 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 - BRENNTAG SOUTHWEST, INC. (078427532)

Registrant - BRENNTAG SOUTHWEST, INC. (078427532)

Establishment

Name	Address	ID/FEI	Business Operations
Brenntag Southwest, Inc.		078427532	manufacture(68812-4934) , pack(68812-4934)

Establishment

Name	Address	ID/FEI	Business Operations
Brenntag Southwest, Inc.		079258886	manufacture(68812-4934) , pack(68812-4934)

Revised: 4/2020

BRENNTAG SOUTHWEST, INC.