

HAND SANITIZER 08- alcohol liquid
U.S. Continental

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.

EnviroTech 8 ounce / 236 ml 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.

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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

J.S. CONTINENTAL 310 Reed Circle • Corona, CA 92679 • 951 808-8888 • Fax 951 808-9999

Please read this proof carefully and indicate any corrections or errors found.

APPROVAL FOR ATTACHED JOB
U.S. Continental is not responsible for any errors or omissions not indicated at this time. Alterations will be charged extra according to time involved in making necessary changes. Please check that all areas have been reviewed and approved, sign and return.
 All text has been proof-read. All bar codes have been scanned for accuracy. Any appropriate warnings are correct.

Customer Signature _____ Date _____

Colors: BLACK PMS 2025 PMS 7686 PMS 032C PMS 107

Printed Size: 6.325 X 9" Corners: Square Round

Materials: Glossy Laminate Paper Laminated UV Coating

Bottle Base: _____
Bottle Lid: _____

ENVIROTECH

BAC STOP™ 4A

HAND SANITIZER

80% ALCOHOL ANTISEPTIC

Alcohol Antiseptic Topical Solution

8 fl. oz./236 ml

Drug Facts

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Alcohol 80% v/v	Antiseptic

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Enviro Tech Chemical Services, Inc.
500 Wilshire Way
Menlo Park, California 94025
300-681-8676
envirotech.com
PRODUCT OF U.S.A.

8 107

LBL4018

002-08

236 mL NDC: 76533-

HAND SANITIZER 08

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76533-002
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:76533-002-08	236 mL in 1 BOTTLE; 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 - U.S. Continental (793141912)

Establishment

Name	Address	ID/FEI	Business Operations
U.S. Continental		793141912	manufacture(76533-002)

Revised: 5/2020

U.S. Continental