

HAND SANITIZER- alcohol liquid

Estron Chemical

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.

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

<p>Alcohol Antiseptic 80% Topical Solution Hand Sanitizer Non-sterile Solution 3.785 Liters</p>	<div style="border: 2px solid black; padding: 20px; margin: 0 auto; width: 80%;"> <p style="font-size: 24px; font-weight: bold; margin: 0;">Hand Sanitizer</p> <hr style="border: 1px solid black;"/> <p style="font-size: 24px; font-weight: bold; margin: 0;">Sprayable Liquid</p> <p style="font-size: 18px; font-weight: bold; margin: 10px 0 0 0;">Easy to Pour</p> <p style="font-size: 18px; font-weight: bold; margin: 0 0 0 0;">80% Alcohol</p> </div>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td colspan="2">Drug Facts</td></tr> <tr> <td style="font-size: 8px;">Active ingredient[s]</td> <td style="font-size: 8px;">Purpose</td> </tr> <tr> <td style="font-size: 8px;">Alcohol 80% v/v.....</td> <td style="font-size: 8px;">Antiseptic</td> </tr> <tr><td colspan="2">Use[s]</td></tr> <tr> <td colspan="2" style="font-size: 8px;">Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.</td> </tr> <tr><td colspan="2">Warnings</td></tr> <tr> <td colspan="2" style="font-size: 8px;">For external use only. Flammable. Keep away from heat or Do not use</td> </tr> <tr> <td colspan="2" style="font-size: 8px;">• in children less than 2 months of age</td> </tr> <tr> <td colspan="2" style="font-size: 8px;">• on open skin wounds</td> </tr> <tr> <td colspan="2" style="font-size: 8px;">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.</td> </tr> <tr> <td colspan="2" style="font-size: 8px;">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr><td colspan="2">Directions</td></tr> <tr> <td colspan="2" style="font-size: 8px;">Spray hand sanitizer directly on hands and rub lotion gently between fingers and palms until dry. Can be applied repeatedly throughout day.</td> </tr> <tr> <td colspan="2" style="font-size: 8px;">Flammable Liquid. Keep out of reach of children. This product is NOT for oral consumption.</td> </tr> <tr><td colspan="2">Other information</td></tr> <tr> <td colspan="2" style="font-size: 8px;">• Store between 15-30C (59-86F)</td> </tr> <tr> <td colspan="2" style="font-size: 8px;">• Avoid freezing and excessive heat above 40C (104F)</td> </tr> <tr><td colspan="2">Inactive ingredients</td></tr> <tr> <td colspan="2" style="font-size: 8px;">glycerin, hydrogen peroxide, purified water USP</td> </tr> </table>	Drug Facts		Active ingredient[s]	Purpose	Alcohol 80% v/v.....	Antiseptic	Use[s]		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 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.		Directions		Spray hand sanitizer directly on hands and rub lotion gently between fingers and palms until dry. Can be applied repeatedly throughout day.		Flammable Liquid. Keep out of reach of children. This product is NOT for oral consumption.		Other information		• Store between 15-30C (59-86F)		• Avoid freezing and excessive heat above 40C (104F)		Inactive ingredients		glycerin, hydrogen peroxide, purified water USP	
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<p>"A Cleaner World" Hand Sanitizer is based on a formulation developed by the World Health Organization to kill germs on hands, therefore improving personal hygiene and reducing the likelihood of transmitting contact-based pathogens. Our product is provided in one-gallon containers to allow for the easy refilling of smaller spray bottles, thereby reducing waste.</p> <p>A portion of the proceeds will go towards COVID-19 relief funds.</p>	 <p>ESTRON CHEMICAL</p>	<p>Since 1976</p>																																						
<p>ESTRON CHEMICAL, INC. 807 North Main Street Calvert City, KY 42029 USA T 270.395.4195</p>	<p>Produced and Packaged in the USA</p>	<p>Label Revision Date: 04212020</p>																																						

3785 mL NDC: 75110-378-10

HAND SANITIZER			
alcohol liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75110-378

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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75110-378-10	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75110-378-20	18927 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 - Estron Chemical (092570407)

Establishment

Name	Address	ID/FEI	Business Operations
Estron Chemical		092570407	manufacture(75110-378)

Revised: 5/2020

Estron Chemical