

COVISAN- ethyl alcohol liquid
Flavorcraft Industries, 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.

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

Antiseptic

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.

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

3.78L NDC: 74593-002-28 - 1 gallon jug



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 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.	
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	

This product is manufactured and labeled in compliance with the Federal Food, Drug and Cosmetic Act (FDA).

Manufactured by Covi Clean, LLC
2123 Watterson Trail, Louisville, KY 40299
sales@coviclean.net



236mL NDC: 74593-002-08 - 8 ounce bottle

	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 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. Directions - Place enough product on hands to cover all surfaces. Rub hands together until dry. - Supervise children under 6 years of age when using the 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	Manufactured by Covi Clean, LLC 2123 Watterson Trail, Louisville, KY 40299 sales@coviclean.net This product is manufactured and labeled in compliance with the Federal Food, Drug and Cosmetic Act (FDA).  FOR EXTERNAL USE ONLY
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208.19L NDC: 74593-002-55 - 55 gallon drum



Hand Sanitizer

with 80% Alcohol



55 GAL (208.19L)

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 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.	
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	

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7 58354 80040 0
FOR EXTERNAL USE ONLY

59mL NDC: 74593-002-02 - 2 ounce bottle

 <p>2 FL OZ (59 mL)</p>	Drug Facts	<p>Manufactured by Covi Clean, LLC 2123 Watterson Trail, Louisville, KY 40299 sales@coviclean.net</p> <p>This product is manufactured and labeled in compliance with the Federal Food, Drug and Cosmetic Act (FDA).</p>  <p>7 58354 80039 4 FOR EXTERNAL USE ONLY</p>	
	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 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.			
Directions			
- Place enough product on hands to cover all surfaces. Rub hands together until dry.			
- Supervise children under 6 years of age when using the 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			

473mL NDC: 74593-002-16 - 16 ounce bottle

 <p>COVISAN™</p> <p><i>Hand Sanitizer</i></p> <p>with 80% Alcohol</p>  <p>16 FL OZ (473 mL)</p>	Drug Facts Active ingredient(s) Alcohol 80% v/v Purpose Antiseptic	Manufactured by Covi Clean, LLC 2123 Watterson Trail, Louisville, KY 40299 sales@coviclean.net This product is manufactured and labeled in compliance with the Federal Food, Drug and Cosmetic Act (FDA).  7 58354 80062 2 FOR EXTERNAL USE ONLY
	Use(s) Hand sanitizer to help reduce bacterial potential on your hands. 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 or 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. 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, purified water USP		

18.9L NDC: 74593-002-99 - 5 gallon pail



Hand Sanitizer

with 80% Alcohol



5 GAL (640 FL OZ) 18.9L

Drug Facts**Active ingredient[s]**

Alcohol 80% v/v

Purpose

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 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.

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

This product is manufactured and labeled in compliance with the Federal Food, Drug and Cosmetic Act (FDA).

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2123 Watterson Trail, Louisville, KY 40299
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FOR EXTERNAL USE ONLY

COVISAN

ethyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74593-002
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
WATER (UNII: 059QF0K00R)	18.425 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74593-002-28	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/13/2020	
2	NDC:74593-002-55	208197 mL in 1 DRUM; Type 0: Not a Combination Product	05/05/2020	
3	NDC:74593-002-99	18927 mL in 1 PAIL; Type 0: Not a Combination Product	04/20/2020	
4	NDC:74593-002-02	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2020	
5	NDC:74593-002-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/08/2020	
6	NDC:74593-002-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/25/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/13/2020	

Labeler - Flavorcraft Industries, Inc. (621632921)**Establishment**

Name	Address	ID/FEI	Business Operations
Flavorcraft Industries, Inc.		621632921	manufacture(74593-002)

Revised: 5/2020

Flavorcraft Industries, Inc.