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)

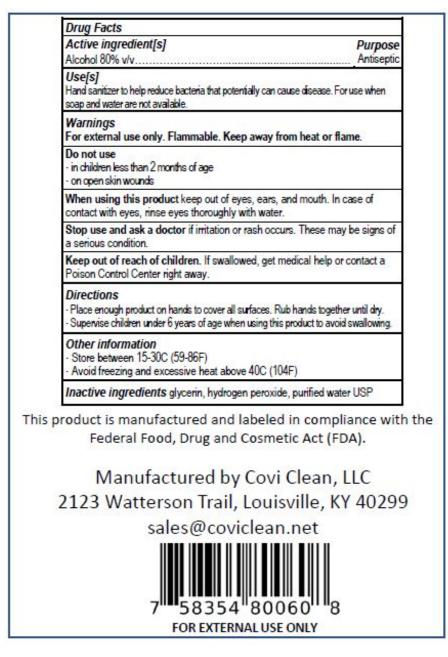
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

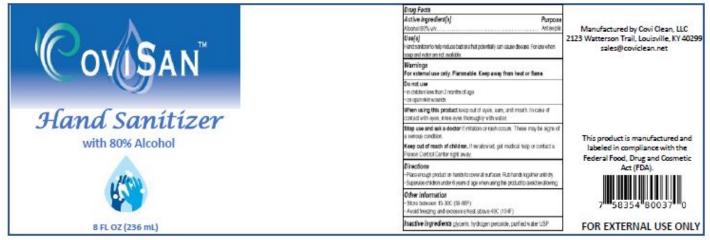
Package Label - Principal Display Panel

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





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



208.19L NDC: 74593-002-55 - 55 gallon drum



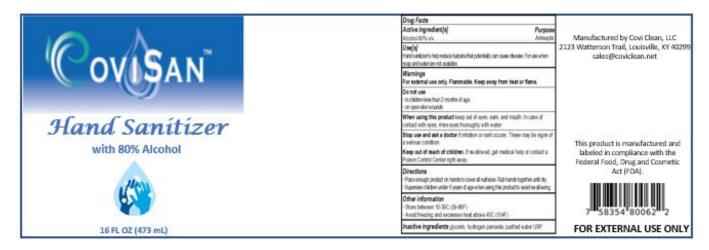
Drug Facts	1				
Active ingredient[s] Alcohol 80%viv.	Purpose Antiseptic				
Use[s] Hand sanitizer to helpreduce bacteria that potentiallyca soap and water are not available.	in cause disease. For use when				
<i>Warnings</i> For external use only. Flammable. Keep away	y from heat or flame.				
) o not use in children lessthan 2 months of age on open skin wounds					
When using this product keep out of eyes, ear contact with eyes, nin se eyes thorough lywith wa					
Stop use and ask a doctor if imitation or rash o a serious condition.	occurs. These maybe signs of				
Keep out of reach of children. If swallowed, ge Poison Control Center right a way.	et medical help or contact a				
Directions • Place enough product on hands to cover all surfaces • Supervise children under 6 years of age when using					
Other information • Store between 15-30C(59-86F) • Avoid freezing and excessive heat above 40C	(104F)				
Inactive ingredients glycerin, hydrogen pero	xide, punified water USP				
is product is manufactured and labeled in Food, Drug and Cosmetic.	Cheffer and the second provide second second second				
Manufactured by Cov	50				
2123 Watterson Trail, Lou					
sales@coviclea	an.net				

FOR EXTERNAL USE ONLY

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



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



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



Active ingredient[s]	Purpos
Alcohol 80% v/v	Antisepti
Use[s] Hand sanifizer to help reduce bacteria that potentially can cause dis soap and water are not available.	sease. For use when
<i>Warnings</i> For external use only. Flammable. Keep away from he	at 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 me contact with eyes, rinse eyes thoroughly with water.	outh. In case of
Stop use and ask a doctor if irritation or rash occurs. The a serious condition.	ese may be signs of
Keep out of reach of children. If swallowed, get medical Poison Control Center right away.	I help or contact a
Directions • Place enough product on hands to cover all surfaces. Rub hand • Supervise children under 6 years of age when using this product	
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COVISAN ethyl alcohol liquid			
Product Information Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74593-002
Route of Administration	TOPICAL	nem code (Source)	100.74333-002

	ctive Ingredie	nt/Ac	tive wolety			
		Ingredient Name		Basis of Strength		Strength
		K9958V	'90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL		80 mL in 100 mL
I	nactive Ingred	ients				
Ingredient Name			Strength			
WATER (UNII: 059QF0KO0R)			18.425 mL in 100 mL			
H	YDRO GEN PERO X	KIDE (U	NII: BBX060AN9V)		$0.125\ mL$ in 100	mL
G	LYCERIN (UNII: PI	DC6A30	C0OX)		1.45 mL in 100 m	ıL
#	Item Code		Package Description	TAT	arketing Start Date	Marketing En Date
Р	ackaging					
					Date	Date
1	NDC:74593-002-		nL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	0.4/1	3/20.20	
1	28	3785 i Produ		04/13	3/2020	
		Produ			3/2020 5/2020	
2	28 NDC:74593-002-	Pro du 20 8 19	et	0 5/0		
2 3	28 NDC:74593-002- 55 NDC:74593-002-	Pro du 20 8 19 18 9 27	rt 7 mL in 1 DRUM; Type 0: Not a Combination Product mL in 1 PAIL; Type 0: Not a Combination Product in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	05/0	5/2020	
2 3 4	28 NDC:74593-002- 55 NDC:74593-002- 99 NDC:74593-002-	Pro dua 20819 18927 59 mL Pro dua	 T mL in 1 DRUM; Type 0: Not a Combination Product mL in 1 PAIL; Type 0: Not a Combination Product in 1 BOTTLE, PLASTIC; Type 0: Not a Combination L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination 	05/0	5/2020 0/2020	
2 3 4 5	28 NDC:74593-002- 55 NDC:74593-002- 99 NDC:74593-002- 02 NDC:74593-002-	Pro due 208 19 18927 59 mL Pro due 473 m	<pre>ct 7 mL in 1 DRUM; Type 0: Not a Combination Product mL in 1 PAIL; Type 0: Not a Combination Product in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination</pre>	0 5/0 0 4/2 0 6/0	5/2020 0/2020 1/2020	
1 2 3 4 5 6	28 NDC:74593-002- 55 NDC:74593-002- 02 NDC:74593-002- 16 NDC:74593-002-	Pro dui 208 19 18927 59 mL Pro dui 473 m Pro dui 236 m	<pre>ct 7 mL in 1 DRUM; Type 0: Not a Combination Product mL in 1 PAIL; Type 0: Not a Combination Product in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination</pre>	0 5/0 0 4/2 0 6/0	5/2020 0/2020 1/2020 8/2020	
2 3 4 5 6	28 NDC:74593-002- 55 NDC:74593-002- 02 NDC:74593-002- 16 NDC:74593-002- 08	Pro dua 208 19 189 27 59 mL Pro dua 473 m Pro dua 236 m Pro dua	et 7 mL in 1 DRUM; Type 0: Not a Combination Product mL in 1 PAIL; Type 0: Not a Combination Product in 1 BOTTLE, PLASTIC; Type 0: Not a Combination et L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination et	0 5/0 0 4/2 0 6/0	5/2020 0/2020 1/2020 8/2020	
2 3 4 5 6	28 NDC:74593-002- 55 NDC:74593-002- 02 NDC:74593-002- 16 NDC:74593-002-	Pro dua 208 19 189 27 59 mL Pro dua 473 m Pro dua 236 m Pro dua	rt 7 mL in 1 DRUM; Type 0: Not a Combination Product mL in 1 PAIL; Type 0: Not a Combination Product in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination ct	0 5/0 0 4/2 0 6/0 0 6/0 0 5/2	5/2020 0/2020 1/2020 8/2020	Marketing End Da

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.