

HAND SANITIZER- alcohol liquid
CFB Michigan 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.

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)

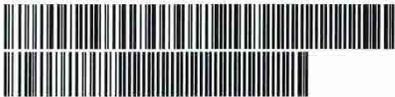
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

sample ltr NDC: 46145-5000-1

CFB, INC.

GROSS WT. LBS KGS NET WT. LBS KGS VOLUME 1 GAL D.O.T. CLASS 55	HAND SANITIZER W NDC 46145-5000-1 Q.A. # * LIQUID HAND SANITIZER UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII 	ADAHD BOT-8OZ
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WARNING



GHS HAZARD AND PRECAUTIONARY STATEMENT

3 2 0 B	<small>FLAMMABLE LIQUID - CATEGORY 3 EYE IRRITATION - CATEGORY 2A</small> <small>FLAMMABLE LIQUIDS AND VAPORS CAUSES SERIOUS EYE IRRITATION</small>
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KEEP AWAY FROM HEAT/SPARKS/OPEN FLAMES/HOT SURFACES - NO SMOKING
KEEP CONTAINER TIGHTLY CLOSED
USE EXPLOSION-PROOF ELECTRICAL/VENTILATING/LIGHTING EQUIPMENT
USE NON-SPARKING TOOLS AND PRECAUTIONARY MEASURES AGAINST STATIC DISCHARGE.
IF ON SKIN/HAIR: WASH CONTAMINATED CLOTHING BEFORE REUSE.
IN CASE OF FIRE: USE DRY CHEMICAL, CARBON DIOXIDE (CO2), FOAM OR WATER SPRAY.
STORE IN WELL-VENTILATED PLACE. KEEP COOL.
DISPOSE OF CONTENTS IN ACCORDANCE WITH ALL APPLICABLE FED., STATE REGULATIONS.

03 E2A

1123 COMMERCE DR. BRISTOL, INDIANA 46507
FAX (574) 848-5963 PHONE (574) 848-5288

3.785 ltr NDC: 46145-5000-2

CFB, INC.

HAND SANITIZER W

NDC 46145-5000-2

Q.A. # *

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAHA GALLON

GROSS WT.

8 LBS

4 KGS

NET WT.

7 LBS

3 KGS

VOLUME

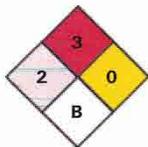
1 GAL

3.785

LTR

D.O.T. CLASS

55



**GHS HAZARD AND
PRECAUTIONARY
STATEMENT**

FLAMMABLE LIQUID - CATEGORY 3
EYE IRRITATION - CATEGORY 2A

FLAMMABLE LIQUIDS AND VAPORS
CAUSES SERIOUS EYE IRRITATION

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WARNING



03 E2A

1123 COMMERCE DR. BRISTOL, INDIANA 46507
FAX (574) 848-5963 PHONE (574) 848-5288

18.925 ltr NDC: 46145-5000-3

CFB, INC.

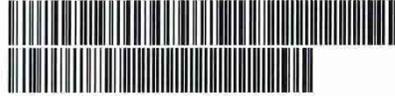
HAND SANITIZER W

NDC 46145-5000-3

Q.A. # *

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



GROSS WT.

38 LBS

17 KGS

NET WT.

35 LBS

16 KGS

VOLUME

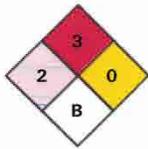
5 GAL

18.925 LTR

D.O.T. CLASS

55

ADAHC PAIL



GHS HAZARD AND PRECAUTIONARY STATEMENT

FLAMMABLE LIQUID CATEGORY 3
EYE IRRITATION CATEGORY 2A

FLAMMABLE LIQUIDS AND VAPORS
CAUSES SERIOUS EYE IRRITATION

WARNING



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03 E2A

1123 COMMERCE DR. BRISTOL, INDIANA 46507
FAX (574) 848-5963 PHONE (574) 848-5288

208.175 ltr NDC: 46145-5000-4

CFB, INC.

HAND SANITIZER W

GROSS WT.

426 LBS

193 KGS

NET WT.

386 LBS

175 KGS

VOLUME

55 GAL

208.175 LTR

D.O.T. CLASS

55

NDC 46145-5000-4

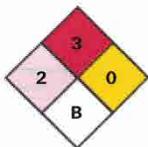
Q.A. # *

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAHB DRUM NB2



WARNING



**GHS HAZARD AND
PRECAUTIONARY
STATEMENT**

FLAMMABLE LIQUID CATEGORY 3
EYE IRRITATION CATEGORY 2A

FLAMMABLE LIQUIDS AND VAPORS
CAUSES SERIOUS EYE IRRITATION

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03 E2A

1123 COMMERCE DR. BRISTOL, INDIANA 46507

FAX (574) 848-5963 PHONE (574) 848-5288

1003.25 ltr NDC: 46145-5000-5

CFB, INC.

HAND SANITIZER W

GROSS WT.

1,999 LBS

907 KGS

NET WT.

1,859 LBS

843 KGS

VOLUME

265 GAL

1,003.025 LTR

D.O.T. CLASS

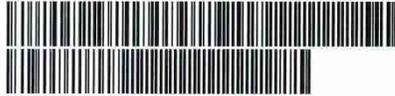
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NDC 46145-5000-5

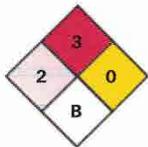
Q.A. # *

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAHE T-275N



GHS HAZARD AND PRECAUTIONARY STATEMENT

**FLAMMABLE LIQUID CATEGORY 3
EYE IRRITATION CATEGORY 2A**

**FLAMMABLE LIQUIDS AND VAPORS
CAUSES SERIOUS EYE IRRITATION**

WARNING



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DISPOSE OF CONTENTS IN ACCORDANCE WITH ALL APPLICABLE FED., STATE REGULATIONS.**

03 E2A

**1123 COMMERCE DR. BRISTOL, INDIANA 46507
FAX (574) 848-5963 PHONE (574) 848-5288**

1211.200 ltr NDC: 46145-5000-6

CFB, INC.

GROSS WT.
2,405 LBS
1,091 KGS
NET WT.
2,245 LBS
1,018 KGS
VOLUME
320 GAL
1,211.200 LTR
D.O.T. CLASS
55

HAND SANITIZER W

NDC 46145-5000-6

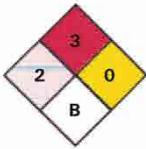
Q.A. # *

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAHF T-330N



WARNING



**GHS HAZARD AND
PRECAUTIONARY
STATEMENT**

FLAMMABLE LIQUID CATEGORY 3
EYE IRRITATION CATEGORY 2A

FLAMMABLE LIQUIDS AND VAPORS
CAUSES SERIOUS EYE IRRITATION

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03 E2A

1123 COMMERCE DR. BRISTOL, INDIANA 46507
FAX (574) 848-5963 PHONE (574) 848-5288

3.785 ltr/gal bulk NDC: 46145-5000-7

CFB, INC.

HAND SANITIZER W

GROSS WT.

7 LBS

3 KGS

NET WT.

7 LBS

3 KGS

VOLUME

1 GAL

3.785 LTR

D.O.T. CLASS

55

NDC 46145-5000-7

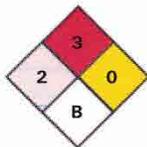
Q.A. # *

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAGZ BULK



GHS HAZARD AND
PRECAUTIONARY
STATEMENT

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EYE IRRITATION CATEGORY 2A

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WARNING



03 E2A

1123 COMMERCE DR. BRISTOL, INDIANA 46507
FAX (574) 848-5963 PHONE (574) 848-5288

Drug facts for all size containers.

Drug Facts

Active Ingredients

Alcohol 80% v/v

Purpose

Antiseptic

Use(s)

Hand sanitizer to help prevent 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

On children less than 2 months old.

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.

Directions: Place enough product on hands to cover all surfaces. Rub hands together until dry.

Supervise children under six years of age when using this product to avoid swallowing.

Other information: Store between 15 to 30C (59 -86F)

Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients: glycerin, hydrogen peroxide, purified water.

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46145-5000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46145-5000-1	0.24 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:46145-5000-2	3.785 L in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:46145-5000-3	18.925 L in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:46145-5000-4	208.175 L in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:46145-5000-5	1003.025 L in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
6	NDC:46145-5000-6	1211.2 L in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
7	NDC:46145-5000-7	2426.185 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; 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 - CFB Michigan Inc. (117507080)

Establishment

Name	Address	ID/FEI	Business Operations
CFB Michigan Inc.		117507080	manufacture(46145-5000)

