

HAND SANI GEL U- 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.

Hand Sanitizer Gel U

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. Hydroxypropylcellulose (.5% v/v)
- e. Sterile distilled water or boiled cold water.
- f. Eucalyptus scent (.2% v/v)

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, hydroxypropylcellulose, eucalyptus oil

Package Label - Principal Display Panel



One North Shore Center, Suite 450, 12 Federal Street, Pittsburgh, PA 15212

SANIDIZE G80

EUCALYPTUS SCENTED GEL SANITIZER

GHS HAZARD AND PRECAUTIONARY STATEMENT

FLAMMABLE CATEGORY 3
EYE IRRITATION CATEGORY 2

KEEP AWAY FROM HEAT/SPARK/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

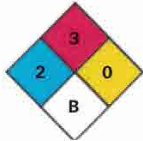
IF ON SKIN (OR HAIR): WASH CONTAMINATED CLOTHING BEFORE REUSE

IF IN EYES: RINSE CAUTIOUSLY WITH WATER FOR SEVERAL MINUTES. REMOVE CONTACT LENSES IF PRESENT AND EASY TO DO. CONTINUE RINSING. IF EYE IRRITATION CONSISTS SEEK MEDICAL ATTENTION.

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 FEDERAL AND STATE REGULATIONS



WARNING



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 <i>For external use only. Flammable. Keep away from heat or flame.</i>	
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 59-86F (15-30C) Avoid freezing and excessive heat above 104F (40C)	
Inactive ingredients glycerin, hydrogen peroxide, hydroxypropyl cellulose, eucalyptus oil, purified water	

GROSS WT
426 LBS
193 KGS

NET WT.
386 LBS
175 KGS

VOLUME
55 GAL
208.175 L

D.O.T. CLASS
55

NDC# 46145-5202-4
LOT#

Drug Fact

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.

CFB, INC.

HAND SANI GEL U

GROSS WT.

7 LBS

3 KGS

NET WT.

7 LBS

3 KGS

VOLUME

1 GAL

3.785 LTR

D.O.T. CLASS

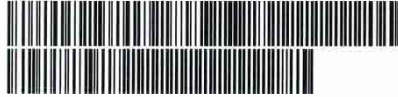
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NDC 46145-5100-7

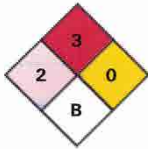
Q.A. # *

GEL HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADALA BULK



**GHS HAZARD AND
PRECAUTIONARY
STATEMENT**

FLAMMABLE LIQUID CATEGORY 3
EYE IRRITATION CATEGORY 2A

FLAMMABLE LIQUIDS AND VAPORS
CAUSES SERIOUS EYE IRRITATION

WARNING



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 OR 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

1211.200 L NDC: 46145-5100-6

CFB, INC.

HAND SANI GEL U

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

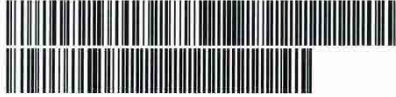
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NDC 46145-5100-6

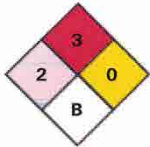
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GEL HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKZ 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

1003.025 L NDC: 46145-5100-5

CFB, INC.

HAND SANI GEL U

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
55

NDC 46145-5100-5

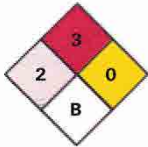
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GEL HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKY 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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03 E2A

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

208.175 L NDC: 46145-5100-4

CFB, INC.

GROSS WT.

426 LBS

193 KGS

NET WT.

386 LBS

175 KGS

VOLUME

55 GAL

208.175 LTR

D.O.T. CLASS

55

HAND SANI GEL U

NDC 46145-5100-4

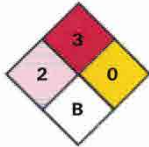
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GEL HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKX 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

18.925 L NDC: 46145-5100-3

CFB, INC.

HAND SANI GEL U

GROSS WT.

38 LBS

17 KGS

NET WT.

35 LBS

16 KGS

VOLUME

5 GAL

18.925 LTR

D.O.T. CLASS

55

NDC 46145-5100-3

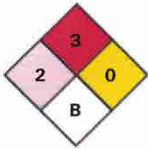
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GEL HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKW PAIL



**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 L NDC: 46145-5100-2

CFB, INC.

HAND SANI GEL U

GROSS WT.

8 LBS
4 KGS

NET WT.

7 LBS
3 KGS

VOLUME

1 GAL
3.785 LTR

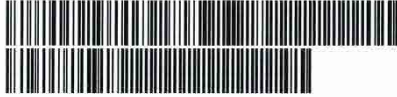
D.O.T. CLASS
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NDC 46145-5100-2

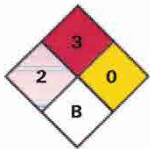
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GEL HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKV GALLON



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

1 L NDC: 46145-5100-1

CFB, INC.

HAND SANI GEL U

GROSS WT.

LBS

KGS

NET WT.

LBS

KGS

VOLUME

1 GAL

NDC 46145-5100-1

Q.A. # *

GEL HAND SANITIZER

LTR

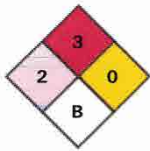
UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII

D.O.T. CLASS

55



ADAKU BOT-8OZ



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

HAND SANI GEL U

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46145-5100
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
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	0.5 L in 100 L
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.2 L in 100 L
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46145-5100-1	1 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:46145-5100-2	3.785 L in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
3	NDC:46145-5100-3	18.925 L in 1 PAIL; Type 0: Not a Combination Product	03/30/2020	
4	NDC:46145-5100-4	208.175 L in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
5	NDC:46145-5100-5	1003.025 L in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
6	NDC:46145-5100-6	1211.2 L in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
7	NDC:46145-5100-7	24224 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		013131732	manufacture(46145-5100)

Revised: 12/2021

CFB Michigan Inc