HAND SANITIZER E- 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 E

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.
- e. Lavender Oil (.02% 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, lavender scent

Package Label - Principal Display Panel



SANIDIZE L80 LAVENDER SCENTED LIQUID 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/VENT/ALTING/LIGHTING EQUIPMENT

USE NON-SPARKING TOOLS AND PRECAUTIONARY MEASURES AGAINST STATIC DISCHARGE

IF ON SKIN (OR HAIR): WASH CONTAMINATED CLOTHING

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

Drug Facts Active ingredient[s] Purpose Alcohol 80% v/v **Use[ର୍ଷ୍ଟ** Hand Sanitzer 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

* On open sam woulds
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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DirectionsPlace 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 a rold swallowing.

Other information Store between 59-86F (15-30C) Avoid freezing and excessive heat above 104F (40C) Inactive ingredients glycerin, hydrogen peroxide, lavender oil, purified

GROSS WT

193 KGS

NET WT. 386 LBS

175 KGS

VOLUME

55 GAL 208,175 L

D.O.T. CLASS

55

NDC# 46145-5001-4

Drug Facts

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.

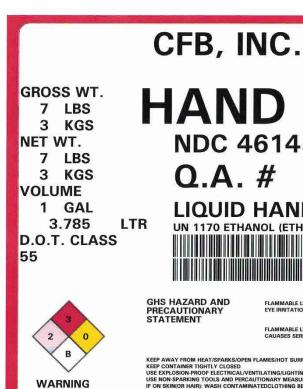
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. **Keep out of reach of children.** If swallowed, get medical help or contact a poison control center. **Directions:** Place enough product on hands to cover all surfaces. Rub hands together until dry.

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.

24224 L NDC: 46145-5001-7



HAND SANITIZER E

NDC 46145-5001-7

Q.A. #

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKM BULK

FLAMMABLE LIQUID CATEGORY 3 EYE IRRITATION CATEGORY 2A

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 PERCAUTIONARY MEASURES AGAINST STATIC DISCHARGE. IF ON SKINION HAIR: WASH CONTAMINATED CLOTHING BEFORE REUSE. INCASE OF FIRE: USE DRY CHEMICAL CARBONDIOXIDE(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

1211.20 L NDC: 46145-5001-6

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

HAND SANITIZER E

NDC 46145-5001-6

Q.A. #

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKL T-330N



GHS HAZARD AND PRECAUTIONARY STATEMENT

FLAMMABLE LIQUID CATEGORY 3 EYE IRRITATION CATEGORY 2A



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 PERCAUTIONARY MEASURES AGAINST STATIC DISCHARGE. IF ON SKINION HAIR): WASH CONTAMINATED CLOTHING BEFORE REUSE. INCASE OF FIRE: USE DRY CHEMICAL/CARBONDIOXIDE(CO2), FOAM OR WATER SPRAY. STORE IN WELL-VENTILATED PLACE. KEEP COOL DISPOSE OF CONTENTS IN ACCORDANCE WITH ALL APPLICABLE FED.,STATE REGULATIONS.



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03 E2A

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

1003.025 L NDC: 46145-5001-5

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

HAND SANITIZER E

NDC 46145-5001-5

Q.A. #

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKK T-275N



GHS HAZARD AND PRECAUTIONARY STATEMENT

FLAMMABLE LIQUID CATEGORY 3 EYE IRRITATION CATEGORY 2A



KEEP AWAY FROM HEAT/SPARKS/OPEN FLAMES/HOT SURFACES - NO SMOKING KEEP AWAY FROM HEAT/SPARKS/OPEN FLAMES/HOT SURFACES - NO SMOKING KEEP CONTAINER TIGHTLY CLOSED USE EXPLOSION-PROOF ELECTRICAL/VENTILATING/ILIGHTING EQUIPMENT USE NON-SPARKING TOOLS AND PERCAUTIONARY MEASURES AGAINST STATIC DISCHARGE. IF ON SKIN/OR HAIR: WASH CONTAMINATEDICTOTHING BEFORE REUSE. INCASE OF FIRE: USE DRY CHEMICAL/CARBONDIOXIDE(O2), FOAM OR WATER SPRAY. STORE IN WELL-VENTILATED PLACE. KEEP COOL DISPOSE OF CONTENTS IN ACCORDANCE WITH ALL APPLICABLE FED.,STATE REGULATIONS.



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03 E2A

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

208.175 L NDC: 46145-5001-4

GROSS WT. 426 LBS 193 KGS NET WT. 386 LBS 175 KGS VOLUME 55 GAL 208.175 D.O.T. CLASS

HAND SANITIZER E

NDC 46145-5001-4

Q.A. #

LIQUID HAND SANITIZER

UN 1170, ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKJ DRUM NB2



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GHS HAZARD AND PRECAUTIONARY STATEMENT

FLAMMABLE LIQUID CATEGORY 3 EYE IRRITATION CATEGORY 2A

FLAMMABLE LIQUIDS AND VAPORS CAUASES SERIOUS EYE IRRITATION



KEEP AWAY FROM HEAT/SPARKS/OPEN FLAMES/HOT SURFACES - NO SMOKING KEEP AWAY FROM HEAT/ISPARKS/OPPB FLAMES/HOT SURFACES - NO SMOKING KEEP CONTAINER TIGHTLY CLOSED .

USE EXPLOSION-PROOF ELECTRICAL/VENTILATING/LIGHTING EQUIPMENT USE NON-SPARKING TOOLS AND PERCAUTIONARY MEASURES AGAINST STATIC DISCHARGE. IF ON SKINIOR HARE: WASH CONTAINANTED/CLOTHING BEFORE REUSE. IF ON SKINIOR HARE: WASH CONTAINANTED/CLOTHING BEFORE REUSE. INCASE OF FIRE USE DRY CHEMICAL/CARBONIOXIDIE(102), FOAM OR WATER SPRAY. STORE IN WELL-VENTILATED PLACE. KEEP COOL DISPOSE OF CONTENTS IN A CCORDANCE WITH ALL APPLICABLE FED.,STATE REGULATIONS.

03 E2A

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

18.925 L NDC: 46145-5001-3



GROSS WT. 38 LBS 17 KGS NET WT. 35 LBS

16 KGS VOLUME 5 GAL

18.925

D.O.T. CLASS

LTR

HAND SANITIZER E NDC 46145-5001-3

Q.A. #

LIQUID HAND SANITIZER

UN 1170, ETHANOL (ETHYL ALCOHOL) 3, PGII

ADAKI PAIL





GHS HAZARD AND PRECAUTIONARY STATEMENT

FLAMMABLE LIQUID CATEGORY 3 EYE IRRITATION CATEGORY 2A

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 PERCAUTIONARY MEASURES AGAINST STATIC DISCHARGE. IF ON SKINION HAIR): WASH CONTAMINATED CLOTHING BEFORE REUSE. INCASE OF FIRE: USE DRY CHEMICAL/CARBONDIOXIDE(CO2), FOAM OR WATER SPRAY. STORE IN WELL-VENTILATED PLACE. KEEP COOL DISPOSE OF CONTENTS IN ACCORDANCE WITH ALL APPLICABLE FED.,STATE REGULATIONS.

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

3.785 L NDC: 46145-5001-2



HAND SANITIZER E NDC 46145-5001-2

LIQUID HAND SANITIZER

UN 1170 ETHANOL (ETHYL ALCOHOL) 3, PGII



ADAKH GALLON



GHS HAZARD AND PRECAUTIONARY STATEMENT

FLAMMABLE LIQUID CATEGORY 3 EYE IRRITATION CATEGORY 2A

FLAMMABLE LIQUIDS AND VAPORS CAUASES SERIOUS EYE IRRITATION

KEEP AWAY FROM HEAT/SPARKS/OPEN FLAMES/HOT SURFACES - NO SMOKING KEEP CONTAINER TIGHTLY CLOSED USE EXPLOSION-PROOF ELECTRICAL/PENTILATING/LIGHTING EQUIPMENT USE NON-SPARKING TOOLS AND PERCAUTIONARY MEASURES AGAINST STATIC DISCHARGE. IF ON SKINGN HARIP: WASH CONTAMINATED/LOTHING BEFORE REUSE. INCASE OF FIRE: USE DRY CHEMICAL_CARBONDIOXIDE(CO2), FOAM OR WATER SPRAY. STORE IN WELL-VENTILATED FLACE. KEEP COLO. DISPOSE OF CONTENTS IN ACCORDANCE WITH ALL APPLICABLE FED.,STATE REGULATIONS.



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

1 L NDC: 46145-5001-1

GROSS WT. LBS

KGS

HAND SANITIZER E

NET WT.

LBS

KGS VOLUME

1 GAL

LTR

D.O.T. CLASS 55

NDC 46145-5001-1

Q.A. #

LIQUID HAND SANITIZER



ADAKG BOT-80Z



WARNING





FLAMMABLE LIQUID CATEGORY 3 EYE IRRITATION CATEGORY 2A

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 PERCAUTIONARY MEASURES AGAINST STATIC DISCHARGE. IF ON SKNINGH ARIR: WASH CONTAMINATED CLOTHING BEFORE REUSE. INCASE OF FIRE: USE DRY CHEMICAL/CARBONDIOXIDE(CO2), FOAM OR WATER SPRAY. STORE IN WELL-VENTILATED PLACE. KEEP COOL.

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

HAND SANITIZER E

alcohol liquid

Product Information

Product Type NDC:46145-5001 HUMAN OTC DRUG **Item Code (Source)**

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
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.02 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- 5001-1	1 L in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020			
2	NDC:46145- 5001-2	3.785 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020			
3	NDC:46145- 5001-3	18.925 L in 1 PAIL; Type 0: Not a Combination Product	03/30/2020			
4	NDC:46145- 5001-4	208.175 L in 1 DRUM; Type 0: Not a Combination Product	03/30/2020			
5	NDC:46145- 5001-5	1003.025 L in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020			
6	NDC:46145- 5001-6	1211.2 L in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020			
7	NDC:46145- 5001-7	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(46145-5001)				

Revised: 12/2021 CFB Michigan Inc