

HAND SANITIZER- alcohol gel
Commercial Beverage Concepts, LLC

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)

Ethyl Alcohol

Purpose

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 ingest or inhale.

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. Condition persists for more than 72 hours.

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

Fragrance (Parfum), Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water

Package Label - Principal Display Panel

237 mL NDC: 75594-021-01

Drug Facts	
Active ingredient(s) Ethyl Alcohol 70% v/v.....	Purpose Antiseptic
Uses: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings <ul style="list-style-type: none">• For external use only: hands• Flammable, keep away from heat or flame• Do not ingest or inhale	
Do not use <ul style="list-style-type: none">• for 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, flush eyes thoroughly with water.	
Stop use and ask a doctor if <ul style="list-style-type: none">• irritation or rash occurs• condition persists for more than 72 hours	
Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none">• Place enough product on hands to cover all surfaces and rub hands together until dry• Supervise children under 6 years of age when using this product	
Other information <ul style="list-style-type: none">• Store between 15 – 30C (59 – 86F)• Avoid freezing and storage above 40C (104F)	
Inactive ingredients – Fragrance (Parfum), Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water	



GEL HAND SANITIZER

FRESH SCENT

ANTISEPTIC

ALCOHOL 70% v/v

Manufactured by:
Commercial Beverage Concepts, LLC
2408 Karbach St., Houston, Texas 77092

8 fl oz. | 237 mL

355mL NDC: 75594-021-07

Drug Facts	
Active ingredient(s) Ethyl Alcohol 70% v/v.....	PurposeAntiseptic
Uses: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
<ul style="list-style-type: none"> For external use only: hands Flammable, keep away from heat or flame Do not ingest or inhale 	
Do not use	
<ul style="list-style-type: none"> for 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, flush eyes thoroughly with water.	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> irritation or rash occurs condition persists for more than 72 hours 	
Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> Place enough product on hands to cover all surfaces and rub hands together until dry Supervise children under 6 years of age when using this product 	
Other information	
<ul style="list-style-type: none"> Store between 15 – 30C (59 – 86F) Avoid freezing and storage above 40C (104F) 	
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GEL HAND SANITIZER

*FRESH
SCENT*

ANTISEPTIC
ALCOHOL 70% v/v

Manufactured by:
Commercial Beverage Concepts, LLC
2408 Karbach St., Houston, Texas 77092

12 fl oz. | 355 mL

473 mL NDC: 75594-021-02

Drug Facts	
Active ingredient(s) Ethyl Alcohol 70% v/v.....	Purpose Antiseptic
Uses: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
<ul style="list-style-type: none"> • For external use only: hands • Flammable, keep away from heat or flame • Do not ingest or inhale 	
Do not use	
<ul style="list-style-type: none"> • for 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, flush eyes thoroughly with water.	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • irritation or rash occurs • condition persists for more than 72 hours 	
Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces and rub hands together until dry • Supervise children under 6 years of age when using this product 	
Other information	
<ul style="list-style-type: none"> • Store between 15 – 30C (59 – 86F) • Avoid freezing and storage above 40C (104F) 	
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GEL HAND SANITIZER

FRESH SCENT

ANTISEPTIC
ALCOHOL 70% v/v

Manufactured by:
Commercial Beverage Concepts, LLC
2408 Karbach St., Houston, Texas 77092

16 fl oz. | 473 mL

946 mL NDC: 75594-021-03

Drug Facts	
Active ingredient(s) Ethyl Alcohol 70% v/v.....	Purpose Antiseptic
Uses: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
<ul style="list-style-type: none"> • For external use only: hands • Flammable, keep away from heat or flame • Do not ingest or inhale 	
Do not use	
<ul style="list-style-type: none"> • for 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, flush eyes thoroughly with water.	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> • irritation or rash occurs • condition persists for more than 72 hours 	
Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> • Place enough product on hands to cover all surfaces and rub hands together until dry • Supervise children under 6 years of age when using this product 	
Other information	
<ul style="list-style-type: none"> • Store between 15 – 30C (59 – 86F) • Avoid freezing and storage above 40C (104F) 	
Inactive ingredients – Fragrance (Parfum), Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water	



GEL HAND SANITIZER

FRESH SCENT

ANTISEPTIC
ALCOHOL 70% v/v

Manufactured by:
Commercial Beverage Concepts, LLC
2408 Karbach St., Houston, Texas 77092

32 fl oz. | 946 mL

1.89 L NDC: 75594-021-04

Drug Facts	
Active ingredient(s) Ethyl Alcohol 70% v/v	Purpose Antiseptic
Uses: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
<ul style="list-style-type: none"> For external use only: hands Flammable, keep away from heat or flame Do not ingest or inhale 	
Do not use	
<ul style="list-style-type: none"> for 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, flush eyes thoroughly with water.	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> irritation or rash occurs condition persists for more than 72 hours 	
Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions	
<ul style="list-style-type: none"> Place enough product on hands to cover all surfaces and rub hands together until dry Supervise children under 6 years of age when using this product 	
Other information	
<ul style="list-style-type: none"> Store between 15 – 30C (59 – 86F) Avoid freezing and storage above 40C (104F) 	
Inactive ingredients – Fragrance (Parfum), Glycerin, Isopropyl Myristate, Polyethylene Glycol/Acrylates Copolymer, Tocopheryl Acetate, Water	



GEL HAND SANITIZER

FRESH SCENT

ANTISEPTIC
ALCOHOL 70% v/v

Manufactured by:
Commercial Beverage Concepts, LLC
2408 Karbach St., Houston, Texas 77092

64 fl oz. | 1.89 L

3.78 L NDC: 75594-021-05

Drug Facts	
Active ingredient(s) Ethyl Alcohol 70% v/v	Purpose Antiseptic
Uses: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
Warnings	
<ul style="list-style-type: none"> For external use only: hands Flammable, keep away from heat or flame Do not ingest or inhale 	
Do not use	
<ul style="list-style-type: none"> for 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, flush eyes thoroughly with water.	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> irritation or rash occurs condition persists for more than 72 hours 	
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Other information	
<ul style="list-style-type: none"> Store between 15 – 30C (59 – 86F) Avoid freezing and storage above 40C (104F) 	
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ANTISEPTIC
ALCOHOL 70% v/v

Manufactured by:
Commercial Beverage Concepts, LLC
2408 Karbach St., Houston, Texas 77092

128 fl oz. | 3.78 L

208 L NDC: 75594-021-06

Product Name:

Modern HHCO



DISTRIBUTED BY:

Modern Chemical, LLC
2408 Karbach St.
Houston, Texas 77092

SIGNAL WORD: DANGER

HAZARD STATEMENTS:

H319 - Causes serious eye irritation.
H225 - Highly flammable liquid and vapour.

BUSINESS NUMBER:

+1 (281) 888-2806

EMERGENCY NUMBER:

CHEMWATCH

+1-877-715-9305

+1-855-237-5573 (toll-free)

PRECAUTION STATEMENTS:

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233 - Keep container tightly closed.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P240 - Ground/bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.
P242 - Use only non-sparking tools.
P243 - Take precautionary measures against static discharge.P370+P378 - In case of fire: Use alcohol resistant foam or normal protein foam for extinction.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.P403+P235 - Store in a well-ventilated place. Keep cool.P501 - Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

LABELING AND CLASSIFICATIONS:

Eye Irritation Category 2A
Flammable Liquid Category 2

TRANSPORTATION:

UN NUMBER:

UN 1987

PROPER SHIPPING NAME:

Alcohols, n.o.s.
(contains ethanol)

HAZARD CLASS: 3

PACKAGING GROUP: III



PICTOGRAM:



55 Gallons | 208 L

LOT #:

Net Weight:

1249L NDC: 75594-021-08

Product Name:

Modern HHCO



DISTRIBUTED BY:

Modern Chemical, LLC
2408 Karbach St.
Houston, Texas 77092

SIGNAL WORD: DANGER

HAZARD STATEMENTS:

H319 - Causes serious eye irritation.
H225 - Highly flammable liquid and vapour.

BUSINESS NUMBER:

+1 (281) 888-2806

EMERGENCY NUMBER:

CHEMWATCH
+1-877-715-9305
+1-855-237-5573 (toll-free)

LABELING AND CLASSIFICATIONS:

Eye Irritation Category 2A
Flammable Liquid Category 2

PRECAUTION STATEMENTS:

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233 - Keep container tightly closed.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P240 - Ground/bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.
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P243 - Take precautionary measures against static discharge.P370+P378 - In case of fire: Use alcohol resistant foam or normal protein foam for extinction.
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P303+P361+P353 - IF ON SKIN (or hair): Remove/take off immediately all contaminated clothing. Rinse skin with water/shower.P403+P235 - Store in a well-ventilated place. Keep cool.P501 - Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

TRANSPORTATION:

UN NUMBER:

UN 1987

PROPER SHIPPING NAME:

Alcohols, n.o.s. (contains ethanol)

HAZARD CLASS: 3

PACKAGING GROUP: III



PICTOGRAM:



330 Gallons | 1249 L

LOT #:
Net Weight:

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75594-021(NDC:77034-002)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 L in 1 L

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLCELLULOSE, UNSPECIFIED (UNII: Z944H5SN0H)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75594-021-01	0.237 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
2	NDC:75594-021-02	0.473 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
3	NDC:75594-021-03	0.946 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
4	NDC:75594-021-04	1.89 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
5	NDC:75594-021-05	3.78 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
6	NDC:75594-021-07	0.354 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/28/2020	
7	NDC:75594-021-06	208 L in 1 DRUM; Type 0: Not a Combination Product	07/28/2020	
8	NDC:75594-021-08	1249 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	07/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/28/2020	

Labeler - Commercial Beverage Concepts, LLC (080925174)

Establishment

Name	Address	ID/FEI	Business Operations
Commercial Beverage Concepts, LLC		080925174	label(75594-021) , pack(75594-021) , relabel(75594-021) , repack(75594-021)

Revised: 7/2020

Commercial Beverage Concepts, LLC