

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.

Active Ingredient(s)

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

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

- 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, 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, PEG-6 (and) AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water

Package Label - Principal Display Panel



GEL HAND SANITIZER



ANTISEPTIC
ALCOHOL 70% v/v

128 fl oz. (3.78L)

DRUG FACTS ACTIVE INGREDIENT[S] | ALCOHOL 70% v/v PURPOSE | ANTISEPTIC

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, PEG-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water	

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



3.78L, NDC: 75594-006-08



GEL HAND SANITIZER



ANTISEPTIC
ALCOHOL 70% v/v

2 oz | 59 ml

DRUG FACTS ACTIVE INGREDIENT[S] | ALCOHOL 70% v/v PURPOSE | ANTISEPTIC

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, PEG-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water	

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2408 Karbach St., Houston, Texas 77092



.059L, NDC: 75594-006-01



GEL HAND SANITIZER



ANTISEPTIC
ALCOHOL 70% v/v

4 oz | 120 ml

DRUG FACTS
ACTIVE INGREDIENT[S] | ALCOHOL 70% v/v
PURPOSE | ANTISEPTIC

Drug Facts	
Active ingredient(s)	Purpose
Ethyl Alcohol 70% v/v.....	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, PEG-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water	

Manufactured by:
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2408 Karbach St., Houston, Texas 77092



.12L, NDC: 75594-006-02



GEL HAND SANITIZER



ANTISEPTIC
ALCOHOL 70% v/v

12 oz | 354ml

DRUG FACTS
ACTIVE INGREDIENT[S] | ALCOHOL 70% v/v
PURPOSE | ANTISEPTIC

Drug Facts	
Active ingredient(s)	Purpose
Ethyl Alcohol 70% v/v	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, PEG-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water	

Manufactured by:
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2408 Karbach St., Houston, Texas 77092



.354L, NDC: 75594-006-04



GEL HAND SANITIZER



ANTISEPTIC
ALCOHOL 70% v/v

8 oz | 237ml

DRUG FACTS
ACTIVE INGREDIENT[S] | ALCOHOL 70% v/v
PURPOSE | ANTISEPTIC

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, PEG-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water	

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



8 50019 69902 9

.237L, NDC: 75594-006-03



GEL HAND SANITIZER



ANTISEPTIC
ALCOHOL 70% v/v

16 oz | 477ml

DRUG FACTS
ACTIVE INGREDIENT[S] | ALCOHOL 70% v/v
PURPOSE | ANTISEPTIC

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, PEG-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water	

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



.477L, NDC: 75594-006-05



GEL HAND SANITIZER



ANTISEPTIC
ALCOHOL 70% v/v

1qt | 946ml

DRUG FACTS
ACTIVE INGREDIENT[S] | ALCOHOL 70% v/v
PURPOSE | ANTISEPTIC

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, PEG-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water	

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



.946L, NDC: 75594-006-06



GEL HAND SANITIZER



ANTISEPTIC
ALCOHOL 70% V/V

64 fl oz. (1.89 L)

DRUG FACTS
ACTIVE INGREDIENT[S] | ALCOHOL 70% V/V
PURPOSE | ANTISEPTIC

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, PEG-6 (and)AMP-Acrylates/Vinyl Isodecanoate Crosspolymer, Water	

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



1.89L, NDC: 75594-006-07

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75594-006(NDC:74221-006)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
RAPIDGEL EZ1 (UNII: 33JH4A7R2K)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75594-006-01	0.059 L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/12/2020	
2	NDC:75594-006-02	0.12 L in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/12/2020	

3	NDC:75594-006-03	0.237 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/12/2020	
4	NDC:75594-006-04	0.354 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/12/2020	
5	NDC:75594-006-05	0.477 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/12/2020	
6	NDC:75594-006-06	0.946 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/12/2020	
7	NDC:75594-006-07	1.89 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/12/2020	
8	NDC:75594-006-08	3.78 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	08/12/2020	

Labeler - Commercial Beverage Concepts, LLC (080925174)

Establishment

Name	Address	ID/FEI	Business Operations
Commercial Beverage Concepts, LLC		080925174	relabel(75594-006) , repack(75594-006) , label(75594-006) , pack(75594-006)

Revised: 8/2020

Commercial Beverage Concepts, LLC