

HAND SANITIZER- alcohol solution

Big Bang Services, L.L.C

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.

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).

1. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (73%, volume/volume (w/w)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
2. Glycerol (1.5% w/w).
3. Hydroxypropylcellulose(Kulcel H) (1.1% w/w).
4. Ceraphyl 31 ester (1.0% w/w)
 - a. Lauryl Alcohol
 - b. Myristyl Alcohol
 - c. Cetyl Alcohol
5. Denatonium benzoate
6. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Alcohol 73% w/w. 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.

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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.

Store between 15-30C (59-86F)

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

purified water USP, hydroxypropyl cellulose, glycerin, myristyl lactate, cetyl lactate, lauryl lactate, denatonium benzoate(bitterant/denaturant)

Alcohol Antiseptic 73% Topical Gel Solution
Antiseptic Hand Rub Non-sterile Solution (5ml)

Drug Facts	
Active ingredients: Ethyl Alcohol (denatured) 13% w/w.....	Proprietary Antiseptic
Uses: Healthcare personnel hand rub to help reduce bacteria that potentially can cause disease.	
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.	
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)	
Contains: Ingredients: purified water USP, hydroxypropyl cellulose, glycerin, myristyl lactate, cetyl lactate, lauryl lactate, denatonium benzoate (bitterant/denaturant)	

Big Bang Services, LLC 1-833-839-8227
Made In Livonia MI 48150 USA

5 ml NDC:75184-003-01

59 ml NDC:75184-003-02

Ethyl Alcohol Antiseptic 73% Topical Gel Solution

Antiseptic Hand Rub Non-sterile Solution / (59 ml) 2oz

Drug Facts

Active ingredient[s]	Purpose
Ethyl Alcohol (Denatured) 73% w/w.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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: purified water USP, hydroxypropyl cellulose, glycerin, myristyl lactate, cetyl lactate, lauryl lactate, denatonium benzoate (bitterant/denaturant)



118 ml NDC:75184-003-04

Ethyl Alcohol Antiseptic 75% Topical Gel Solution

Antiseptic Hand Rub Non-sterile Solution (118 ml) 4oz

Drug Facts

Active ingredient[s]	Purpose
Ethyl Alcohol (Denatured) 73% w/w.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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: purified water USP, hydroxypropyl cellulose, glycerin, myristyl lactate, cetyl lactate, lauryl lactate, denatonium benzoate (bitterant/denaturant)



237 ml NDC:75184-003-08

Ethyl Alcohol Antiseptic 73% Topical Gel Solution

Antiseptic Hand Rub Non-sterile Solution / 237 ml / 8oz

Drug Facts

Active ingredient[s]	Purpose
Ethyl Alcohol (Denatured) 73% w/w.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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: purified water USP, hydroxypropyl cellulose, glycerin, myristyl lactate, cetyl lactate, lauryl lactate, denatonium benzoate (bitterant/denaturant)



3785 ml NDC:75184-003-10

Ethyl Alcohol Antiseptic 73% Topical Gel Solution

Antiseptic Hand Rub Non-sterile Solution (3785 ml) 1 gallon

Drug Facts

Active ingredient[s]	Purpose
Ethyl Alcohol (Denatured) 73% w/w.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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.

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

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Other information

• Store between 15-30C (59-86F)

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

Inactive ingredients: purified water USP, hydroxypropyl cellulose, glycerin, myristyl lactate, cetyl lactate, lauryl lactate, denatonium benzoate (bitterant/denaturant)



HAND SANITIZER

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75184-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2391 mL in 3785 mL

Inactive Ingredients

Ingredient Name	Strength
CETYL LACTATE (UNII: A7EVH2RK4O)	0.01 mL in 3785 mL
MYRISTYL LACTATE (UNII: 1D822OC34X)	0.05 mL in 3785 mL
GLYCERIN (UNII: PDC6A3C0OX)	70 mL in 3785 mL
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	36 mL in 3785 mL
LAURYL LACTATE (UNII: G5SU0BFK7O)	0.08 mL in 3785 mL
WATER (UNII: 059QF0K00R)	754 mL in 3785 mL
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	0.02 mL in 3785 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75184-003-01	5 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/11/2020	
2	NDC:75184-003-02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/11/2020	
3	NDC:75184-003-08	237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/11/2020	
4	NDC:75184-003-10	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
5	NDC:75184-003-04	118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	05/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/11/2020	

Labeler - Big Bang Services, L.L.C (062278201)

Registrant - Big Bang Services, L.L.C (062278201)

Establishment

Name	Address	ID/FEI	Business Operations
Big Bang Services, L.L.C		062278201	manufacture(75184-003)

Revised: 5/2020

Big Bang Services, L.L.C