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.

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 Poison Control Center right away.

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)

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	(Denatured) 13 % www	1 ape 50 Defensio
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Alcohol Antiseptic 73% Topical Gel Solution

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

Ethly Alcohol Antiseptic 73% Topical Gel Solution Antiseptic Hand Rub Non-sterile Solution (59 ml) 202

Drug Facts	×			
Active ingredient[s]	Purpose			
Ethyl Alcohol (Denatured) 73% w/w	Antiseptic			
Use a Health care personnel hand rub to help reduce bacteria that potentially can c	ause disease.			
Waminge	1			
For external use only. Flommable, Keep away from heat or flome				
Donot 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 togeth	er until dry.			
 Supervise children under 6 years of age when using this product to avoid swallowi 	ng.			
Other Information				
Store between 15-3DC (59-86F)				
 Avoid freezing and excessive heat above 4DC (1D4F) 				
inactive ingrediente: purified water USP, hydroxypropyl cellulose, glycerin, myristyl la	ictate,			
cetyl lactate, lau ryl lactate, den atonium benzoate(bitteran t/denaturant)	185			



118 ml NDC:75184-003-04

Ethly Alcohol Antiseptic 73% Topical Gel Solution Antiseptic Hand Rub Non-sterile Solution (118 ml) 4oz

Drug Facts	
	_
Active ingredient[s] Purpose	
Ethyl Alcohol (Denatured) 73% w/wAntiseptic	× -
Use [a] Health care personnel hand rub to help reduce bacteria that potentially can cause disease	
Waming s	0
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 eye	25
thoroughly with water.	121923
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	ight
away.	17. AN
Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry.	100
 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 4DC (1D4F)	
inactive ingredients: purified water USP, hydroxypropyl cellulose, glycerin, myristyl lactate,	
cetyl lactate, lau ryl lactate, den atonium benzoate(bitteran t/denaturant)	- 8



237 ml NDC:75184-003-08

Ethly Alcohol Antiseptic 73% Topical Gel Solution Antiseptic Hand Rub Non-sterile Solution (237 ml) 802

Drug Facts	8			
Active ingredient[s]	Purpose			
Ethyl Alcohol (Denatured) 73% w/w	Antiseptic			
Uce[a] Health care personnel hand rub to help reduce bacteria that potentially can	cause disease.			
Waminge	0			
For external use only. Flammable, Keep away from heat or flame				
Do not use • in child ren 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 C				
away.				
Directions • Place enough production hands to cover all surfaces. Rub hands toget	her until dry.			
 Supervise children under 6 years of age when using this product to avoid swallow 	ring.			
Other Information				
Store between 15-3DC (59-86F)				
 Avoid freezing and excessive heat above 4DC (1D4F) 				
inactive ingredienta: purified water USP, hydroxypropyl cellulose, glycerin, myristyl l	actate,			
cetyl lactate, lau ryl lactate, den atonium benzoate(bitteran t/denaturant)				



3785 ml NDC:75184-003-10

Ethly Alcohol Antiseptic 73% Topical Gel Solution Antiseptic Hand Rub Non-sterile Solution (3785 ml) 1 gallon

Drug Facts	8			
Active ingredient[s]	Purpose			
Ethyl Alcohol (Denatured) 73% w/w	Antiseptic			
Use[a] Health care personnel hand rub to help reduce bacteria that potentially can c	ause disease.			
Warninge	9			
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	eves, rin se eves			
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 Co				
away.				
Directions • Place enough product on hands to cover all surfaces. Rub hands togeth	her until dry.			
 Supervise children under 6 years of age when using this product to avoid swallowing the state of the state of	ing.			
Other Information				
 Store between 15-3DC (59-86F) 				
 Avoid freezing and excessive heat above 4DC (1D4F) 				
inactive ingredienta: purified water USP, hydroxypropyl cellulose, glycerin, myristyl la	ictate,			
cetyl lactate, lauryl lactate, den atonium benzoate(bitterant/denaturant)	2. E			



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) (ALC	COHOL - UNII:3K9958V90M)		ALCOHOL	2391mL in $3785mL$	

Inactive Ingredients					
Ingredient Name	Strength				
CETYL LACTATE (UNII: A7EVH2RK4O)	0.01mL 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: 059QF0KO0R)	754 mL in 3785 mL				
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	$0.02\ mL$ in 3785 mL				

Packaging

#	Item Code	eem Code Package Description Marketing Star Date		Marketing End Date		
1	NDC:75184-003- 01	5 mL i	in 1 BOTTLE, SPRAY; Type 0: Not a Combination Produ	ct 05/11/2020		
2	NDC:75184-003- 02	59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		n 05/11/2020		
3	NDC:75184-003- 08	75184-003- 237 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		on 05/11/2020		
4	NDC:75184-003- 10	⁰³⁻ 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product		05/11/2020		
5	NDC:75184-003- 04	C:75184-003- 118 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		on 05/11/2020		
N	Marketing Information					
	Marketing Categ	ory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
0	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