

HAND SANITIZER- alcohol gel

Draga Laboratories

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

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)

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

Package Label - Principal Display Panel

LIGHTNING LABELS CUSTOM LABELS AND STICKERS	Client: Draga Laboratories, LLC	Job Number: 2004869088003	Date: 04-15-20
	Product: White Bopp	Quantity: Permanent	Version: Right Off - Gap 0.125
NOTE: Artwork is rotated to reflect roll direction once finished. Magenta keyline indicates the finished label size of 4 in. w x 6 in. h and will not print.			



DRAGA
LABORATORIES, LLC

Draga Laboratories
Hand Sanitizer
128 fl oz

Kills 99.9% Bacteria and Germs

Manufactured by Draga Laboratories
Atlanta, GA 30336
(404)762-1131 www.dragalaboratories.com

Drug Facts	
Active Ingredients	80% v/v
Ethyl Alcohol	
Antiseptic Uses 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 - 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 thoroughly with water. Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
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 (104C).	
Inactive Ingredients Acrylates/C10-30 Alkyl Alkylate Crosspolymer, Algin, Aloe Barbaderis Leaf Juice, Aminomethyl Propanol, Aqua (Water)	

LIGHTNING LABELS DESIGN, LABELS AND DECORATION	Client: Draga Laboratories, LLC	Job Number: 200486908003	Date: 04-15-20
	Product: White Bopp	Material: Permanent	Usage: Right Off - Gap 0.125

NOTE: Artwork is related to reflect roll direction once finished. Magenta keyline indicates the finished label size of 4 in. w x 6 in. h and will not print.



Draga Laboratories
Hand Sanitizer
64 fl oz
Kills 99.9% Bacteria and Germs
 Manufactured by Draga Laboratories
 Atlanta, GA 30336
 (404)762-1131 www.dragalaboratories.com

Drug Facts	
Active Ingredients	80% v/v
Ethyl Alcohol	
Antiseptic Uses	
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 - 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 thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.	
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 (104C).	
Inactive Ingredients	
Acrylates/C10-30 Alkyl Alkylate Croscopolymer, Algin, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Aqua (Water)	

Client:	Job Number:	Adhesive:	Paper Type:	CUTTING LABELS AND STICKERS LIGHTNING LABELS PRINTED LIGHTNING MAT
Date:	Unwind:			

Drug Facts	
Active Ingredients Ethyl Alcohol	80% 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 For external use only. Flammable. Keep away from heat or flame. Do not use - 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 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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Other Information Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104C).	
Inactive Ingredients Acrylates/C10-30 Alkyl Alkylate Crosspolymer, Algin, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Aqua (Water)	



Draga Laboratories
Hand Sanitizer
8 fl oz

Kills 99.9% Bacteria and Germs

Manufactured by Draga Laboratories
Atlanta, GA 30336

(404)762-1131 www.dragalaboratories.com

236.58 mL NDC: 75748-4490-2

HAND SANITIZER

LIGHTNING LABELS PRINTED LIGHTNING MARK		Client:	Job Number:	Label Name:	Adhesive:	Paper Type:	Unwind:	Date:

Drug Facts	
Active Ingredients	80% v/v Ethyl Alcohol
Antiseptic Uses	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 - 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 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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DRAGA
LABORATORIES, LLC

Draga Laboratories
Hand Sanitizer
8 fl oz

Kills 99.9% Bacteria and Germs

Manufactured by Draga Laboratories
Atlanta, GA 30336
(404)762-1131 www.dragalaboratories.com

alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75748-4490	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)		ALCOHOL	80 mL in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			0.1 mL in 100 mL	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			0.5 mL in 100 mL	
ALOE (UNII: V5VD430YW9)			0.36 mL in 100 mL	
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75748-4490-4	10000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75748-4490-0	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
3	NDC:75748-4490-1	10000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
4	NDC:75748-4490-2	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
5	NDC:75748-4490-3	10000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
6	NDC:75748-4490-5	100 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
7	NDC:75748-4490-6	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
8	NDC:75748-4490-7	10000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
9	NDC:75748-4490-8	10000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	03/30/2020	
10	NDC:75748-4490-9	10000 mL in 1 BOTTLE, DISPENSING; 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 - Draga Laboratories (610096534)

Establishment

Name	Address	ID/FEI	Business Operations
Draga Laboratories		610096534	manufacture(75748-4490) , repack(75748-4490)

Revised: 5/2020

Draga Laboratories