## HAND SANITIZER- alcohol gel HAND SANITIZER TROPICAL SCENT- alcohol gel Clearbrooke Technologies 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.

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### **Active Ingredient(s)**

Ethyl Alcohol 70% v/v. Purpose: Antiseptic

## **Purpose**

Antiseptic

### Use[s]

- To decrease bacteria on skin that could cause disease
- Recommended for repeated use when soap and water are not available.

#### **Directions**

- Wet hands thoroughly with product and allow it to dry without wiping
- For children under 6 years of age use only under adult supervision
- not recommended for infants

### **Warnings**

For external use only: hands.

Flammable. Keep away from heat or flame

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Avoid contact with broken skin

Do not inhale or ingest

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.

#### Other information

- Do not store above 105F
- may discolor some fabrics
- harmful to wood finishes and plastics

## **Inactive ingredients**

### Package Label - Principal Display Panel

# **Hand Sanitizer**

## Non-sterile Solution

## Alcohol Antiseptic 70% **Topical Solution**

### Drug Facts

Active Ingredient[s]

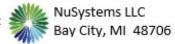
Purpose

Ethyl Alcohol 70% ...... Antiseptic

#### Uses[s]

- ▲ To decrease bacteria on skin that could cause disease
- ▲ Recommended for repeated use when soap and water are not available.

Distributed by:



16 oz

16 oz NDC: 75366-330-01

#### Directions

▲ Wet hands thoroughly with product and allow to dry without wiping A For children under 6 use only under adult supervision A not recommended for infants

#### Warnings

For external use only: hands.

Flammable. Keep away from heat and flame.

When using this product \( \text{\$\text{\$\text{\$\text{\$keep out of eyes.}}} \) In case of contact with eyes, rinse eyes thoroughly with water ▲ avoid contact with broken skin **\( \Lambda \)** do not inhale or ingest

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.

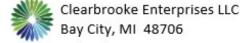
### Other Information

▲ Do not store above 105°F ▲ may discolor some fabrics ▲ harmful to wood finishes and plastics

### **Inactive Ingredients**

Glycerin, purified water; Polylacrylamide, C13-14 isoparaffin Laureth -7

Manufactured by:



# **Hand Sanitizer Gel**

## Non-sterile Solution

## Alcohol Antiseptic 70% Topical Solution

Active Ingredient[s]	Purpose
Ethyl Alcohol 70%	Antiseptic
Uses[s]	
▲ To decrease bacteria on skin that could cause dise:	ase
A Recommended for repeated use when soap and w	ater are not available.
Warnings	
For external use only: hands.	
Flammable. Keep away from heat and flame.	
When using this product $\triangle$ keep out of eyes. In case of o thoroughly with water $\triangle$ avoid contact with broken skin.	
Stop use and ask a doctor if A irritation or rash occurs A more than 72 hours	condition persists for
Keep out of reach of children. If swallowed get medic Poison Control Center right away.	al help or contact a
Directions	
▲ Wet hands thoroughly with product and allow to d	ry without wiping
▲ For children under 6 use only under adult supervisi	ion
▲ not recommended for infants	
Other Information	
▲ Do not store above 105°F ▲ may discolor some fabrics finishes and plastics	harmful to wood
Inactive Ingredients	
Purified water; Glycerin; Polylacrylamide, C13-14 isonaraf	fin Laureth -7

Distributed by:

32 oz

NuSystems LLC Bay City, MI 48706 Manufactured by: Clearbrooke Enterprises LLC Bay City, MI 48706

32 oz NDC: 75366-330-02

## **Hand Sanitizer**

Non-sterile Solution Alcohol Antiseptic 70% Topical Solution

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Drug	racts

#### Usesís

- ▲ To decrease bacteria on skin that could cause disease
- ▲ Recommended for repeated use when soap and water are not available.

#### Warnings

For external use only: hands.

Flammable. Keep away from heat and flame.

When using this product ▲ keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water ▲ avoid contact with broken skin ▲ do not inhale or ingest

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

- ▲ Wet hands thoroughly with product and allow to dry without wiping
- ▲ For children under 6 use only under adult supervision
- ▲ not recommended for infants

#### Other Information

▲ Do not store above 105°F ▲ may discolor some fabrics ▲ harmful to wood finishes and plastics

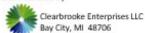
### **Inactive Ingredients**

330 Gallon

Purified water; Glycerin; Polylacrylamide, C13-14 isoparaffin Laureth -7

Distributed by:

NuSystems LLC Bay City, MI 48706 Manufactured by



330 gal NDC: 75366-330-03

## NuSystems LLC Hand Sanitizer

16oz Tropical Scent

Non-sterile Solution Alcohol Antiseptic 70% Topical Solution

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Active Ingredient[s]

Purpose

Ethyl Alcohol 70% ..

. Antiseptic

#### Uses[s]

▲ To decrease bacteria on skin that could cause disease

Recommended for repeated use when soap and water are not available.

#### Directions

▲ Wet hands thoroughly with product and allow to dry without wiping

▲ For children under 6 use only under adult supervision ▲ Not recommended for infants

### Warnings

For external use only: hands. DO NOT INGEST

Flammable. Keep away from heat and flame.

When using this product ▲ keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water ▲ avoid contact with broken skin ▲ do not inhale or ingest

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.

#### Other Information

▲ Do not store above 105°F ▲ may discolor some fabrics ▲ harmful to wood finishes and plastics

#### Inactive Ingredients

Glycerin, purified water; Polylacrylamide, C13-14 isoparaffin, Laureth -7

Manufactured by

Clearbrooke Enterprises LLC Bay City Michigan 48706



16 oz NDC 75366-331-01

## NuSystems LLC **Hand Sanitizer**

32oz Tropical Scent

Non-sterile Solution Alcohol Antiseptic 70% **Topical Solution** 

Active Ingredient[s]

Purpose

Ethyl Alcohol 70% ..

#### Uses[s]

▲ To decrease bacteria on skin that could cause disease

A Recommended for repeated use when soap and water are not

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#### Warnings

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Flammable. Keep away from heat and flame.

When using this product ▲ keep out of eyes. In case of contact with eyes, rinse eyes thoroughly with water A avoid contact with broken skin 🛦 do not inhale or ingest

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.

#### Other Information

▲ Do not store above 105°F ▲ may discolor some fabrics ▲ harmful to wood finishes and plastics Inactive Ingredients

Glycerin, purified water; Polylacrylamide, C13-14 isoparaffin, Laureth -7

Manufactured by

Clearbrooke Enterprises LLC Bay City Michigan 48706



32 oz NDC 75366-331-02

# **Hand Sanitizer Gel**

## 330 Gal Tropical Scent Non-sterile Solution

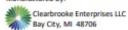
## Alcohol Antiseptic 70% Topical Solution

Active Ingredient(s)	Purpose
Ethyl Alcohol 70%	Antiseptic
Uses[s]	
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Warnings	
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Keep out of reach of children. If swallowed get med	dical help or contact a
Poison Control Center right away.	
Directions	
▲ Wet hands thoroughly with product and allow to	dry without wiping
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Other Information	23
▲ Do not store above 105°F ▲ may discolor some fabr	ics A harmful to wood
finishes and plastics	
Inactive Ingredients	
Purified water; Glycerin; Polylacrylamide, C13-14 isopar	raffin Laureth -7

330 Gal



Manufactured by:



330 gal NDC 75366-331-03

## HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75366-330	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients			
Ingredient Name	Strength		
LAURETH-7 (UNII: Z95S6G8201)			
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL		
WATER (UNII: 059QF0KO0R)			
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)			
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)			

	Packaging				
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:75366-330- 01	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020		
	NDC:75366-330- 02	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020		
	NDC:75366-330- 03	1249 190 mL in 1 TANK; Type 0: Not a Combination Product	04/23/2020		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	04/23/2020		

## HAND SANITIZER TROPICAL SCENT

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75366-331
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
ETHYL METHYLPHENYLGLYCIDATE (UNII: UD51D5KR4A)				
LAURETH-7 (UNII: Z95S6G8201)				
GLYCERIN (UNII: PDC6A3C0OX)	3 mL in 100 mL			
WATER (UNII: 059QF0KO0R)				
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)				
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)				
COUMARIN (UNII: A4VZ22K1WT)				
METHYL CINNAMATE (UNII: 533CV2ZCQL)				
ETHYL MALTOL (UNII: L6Q8K29L05)				
ALLYL HEXANO ATE (UNII: 3VH8 4A363D)				

Packaging			
# Itam Cada	Daglaga Dagazintian	Marketing Start	Marketing End

t Helli Coue	Package Description	Date	Date
NDC:75366-331- 01	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
NDC:75366-331- 02	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
NDC:75366-331- 03	1249 190 mL in 1 TANK; Type 0: Not a Combination Product	04/30/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/30/2020	

## Labeler - Clearbrooke Technologies LLC (006493200)

Establishment			
Name	Address	ID/FEI	Business Operations
Clearbrooke Technologies LLC		006493200	manufacture(75366-330, 75366-331), label(75366-330, 75366-331), pack(75366-330, 75366-331)

Revised: 4/2020 Clearbrooke Technologies LLC