

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.

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

Glycerin, purified water, Polyacrylamide, C13 - 14 isoparaffin, Laureth-7

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:  NuSystems LLC
Bay City, MI 48706

16 oz

16 oz NDC: 75366-330-01

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. 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 <u>skin</u> ▲ 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; <u>Polyacrylamide</u> , <u>C13-14 isoparaffin</u> , <u>Laureth -7</u>

Manufactured by:  Clearbrooke Enterprises LLC
Bay City, MI 48706

Hand Sanitizer Gel

Non-sterile Solution

Alcohol Antiseptic 70%

Topical Solution

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Inactive ingredients	
Purified water; Glycerin; Polyacrylamide, C13-14 isoparaffin Laureth-7	

32 oz NDC: 75366-330-02

32 oz

Distributed by:



NuSystems LLC
Bay City, MI 48706

Manufactured by:



Clearbrooke Enterprises LLC
Bay City, MI 48706


Hand Sanitizer

Non-sterile Solution
Alcohol Antiseptic 70%
Topical Solution

Drug Facts	
Active Ingredient[s]	Purpose
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Inactive Ingredients	
Purified water; Glycerin; Polyacrylamide, C13-14 isoparaffin Laureth -7	

330 Gallon

Distributed by:
 NuSystems LLC
Bay City, MI 48706

Manufactured by
 Clearbrooke Enterprises LLC
Bay City, MI 48706

330 gal NDC: 75366-330-03

NuSystems LLC Hand Sanitizer

16oz Tropical Scent

Non-sterile Solution
Alcohol Antiseptic 70%
Topical Solution

Drug Facts	
Active Ingredient[s]	Purpose
Ethyl Alcohol 70%	Antiseptic
Uses[s]	
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Inactive Ingredients	
Glycerin, purified water; Polyacrylamide, 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

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Manufactured by



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Bay City Michigan 48706



32 oz NDC 75366-331-02

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330 Gal Tropical Scent
Non-sterile Solution

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

330 Gal

Distributed by:
NuSystems LLC
Bay City, MI 48706

Manufactured by:
Clearbrooke Enterprises LLC
Bay City, MI 48706

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
1	NDC:75366-330-01	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
2	NDC:75366-330-02	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2020	
3	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: 5D6TC4BRVW)	
COUMARIN (UNII: A4VZ22K1WT)	
METHYL CINNAMATE (UNII: 533CV2ZCQL)	
ETHYL MALTOL (UNII: L6Q8K29L05)	
ALLYL HEXANOATE (UNII: 3VH84A363D)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:75366-331-01	473.176 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
2	NDC:75366-331-02	946.353 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	
3	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