HAND SANITIZER- ethyl alcohol gel
Hans Manufacturer Inc.

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 - Gel75

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 ingredients in the preparation of the product (percentage in final product formulation):

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, 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 (0.5% v/v).
c. Carbomer (0.3% v/v).
d. Triethanolamine (0.3% v/v).
e. Aloe Barbadensis Leaf Extract (0.2% v/v)
f. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients.

Active Ingredient(s)

Alcohol 75% 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.

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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)

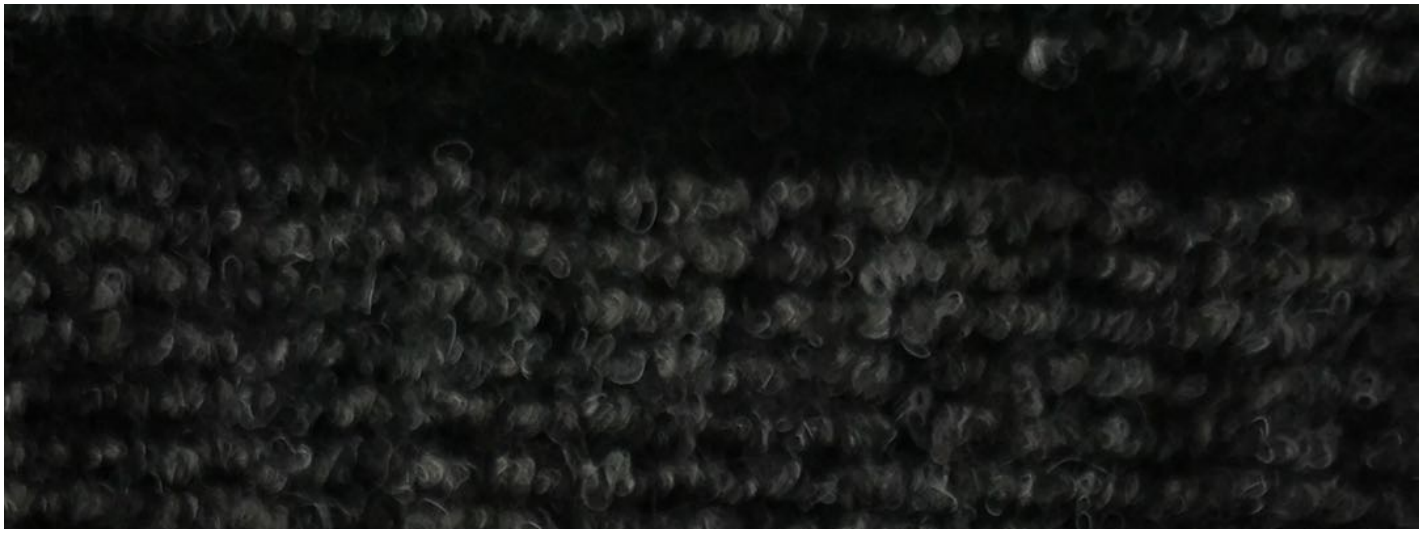
Inactive ingredients

purified water USP, glycerin, carbomer, triethanolamine, aloe barbadensis leaf juice

Package Label - Principal Display Panel

30 mL NDC: 74496-9751-1


DIANJIE®
75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)
• EFFECTIVE STERILIZATION 99.9%
• DISPOSABLE ANTIBACTERIAL DISINFECTANT
NET CONTENT:30ML



Drug Facts

Active ingredient[s] **Purpose**

Ethyl Alcohol 75% v/v---------- Antiseptic

Use[s]

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Other information

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

Water(Aqua),Carbomer,Glycerin,Triethanolamine,Aloe Barbadensis Leaf Juice.

Questions and comments? Tel: 800-654-0957

HHSG2004X

EXP:04/2022

Drug Facts

Active ingredient[s] **Purpose**

Ethyl Alcohol 75% v/v---------- Antiseptic

Use[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

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Inactive ingredients

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Questions and comments? Tel: 800-654-0957

HHSG2004X

EXP:04/2022

60ml NDC: 74496-9751-2


Drug Facts
Active ingredient[s] Purpose
Ethyl Alcohol 75% v/v ---------- Antiseptic
Use[s]
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.
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
Water(Aqua),Carbomer,Glycerin,Triethanolamine,Aloe Barbadensis Leaf Juice
Questions and comments? Tel:1-800-654-0957
HHSG2004X
EXP: 04/2022

100ml NDC: 74496-9751-3


DIANJIE®
75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)
• EFFECTIVE STERILIZATION 99.9%
• DISPOSABLE ANTIBACTERIAL DISINFECTANT
NET CONTENT: 100ML

HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:74496-9751
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.3 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.2 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74496-9751-1	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
2	NDC:74496-9751-2	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
3	NDC:74496-9751-3	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

Labeler - Hans Manufacturer Inc. (787300008)

Establishment

Name	Address	ID/FEI	Business Operations
Boss (Huizhou) Medical & Health Products Co., Ltd.		554530185	manufacture(74496-9751)

Establishment

Name	Address	ID/FEI	Business Operations
Hans Manufacturer Inc.		787300008	label(74496-9751)

Revised: 4/2020 Hans Manufacturer Inc.