

HAND SANITIZER- ethyl alcohol gel
Boss (Huizhou) Medical & Health Products Co., Ltd.

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.

Disinfectant 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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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

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

Package Label - Principal Display Panel

30 mL NDC: 77313-975-11





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.

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Directions

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- 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 Barbadosensis Leaf Juice.

Questions and comments? Tel: 800-654-0957

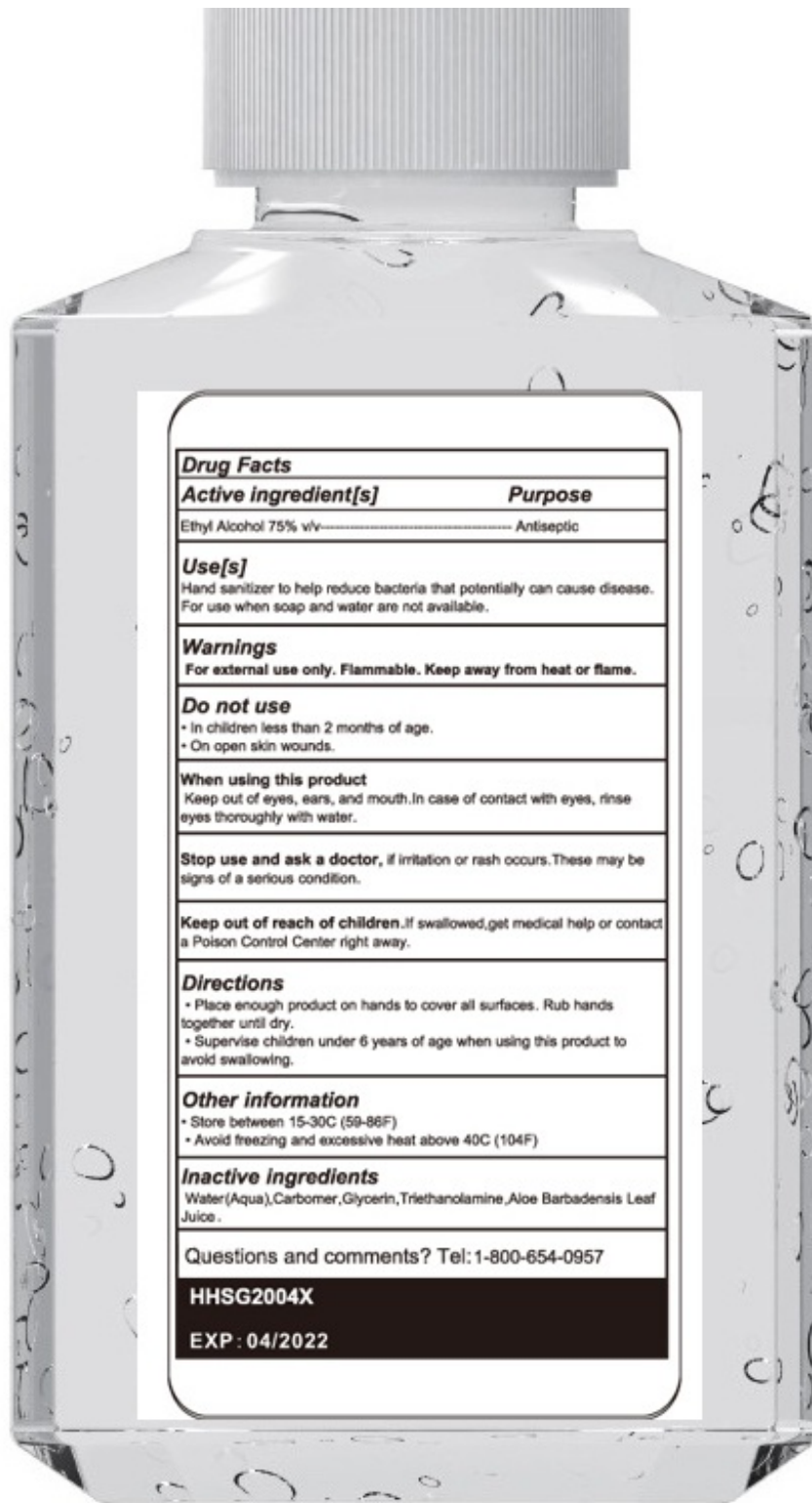
HHS2004X

EXP:04/2022

Back

60 mL NDC: 77313-975-12





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



DIANJIE[®]

75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)



- EFFECTIVE STERILIZATION 99.9%
- DISPOSABLE ANTIBACTERIAL DISINFECTANT



- 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.



Product Name : alcohol disinfectant
Brand :Dianjie

Specification : 100ML

Executive standard: Q / HZBOSS
005-2020

Health license No.: YWXZZ [2019] -
09-0004

Manufacturer: Boss(Huizhou)
Medical & Health Products Co., Ltd.

Production address: Baishida
Science and Technology Park,
Boluo County, Huizhou City,
Guangdong Province

Company website: www.bosshz.com

Validity: 2 years

Batch number and production date :
See the bottle.



200 mL NDC: 77313-975-14

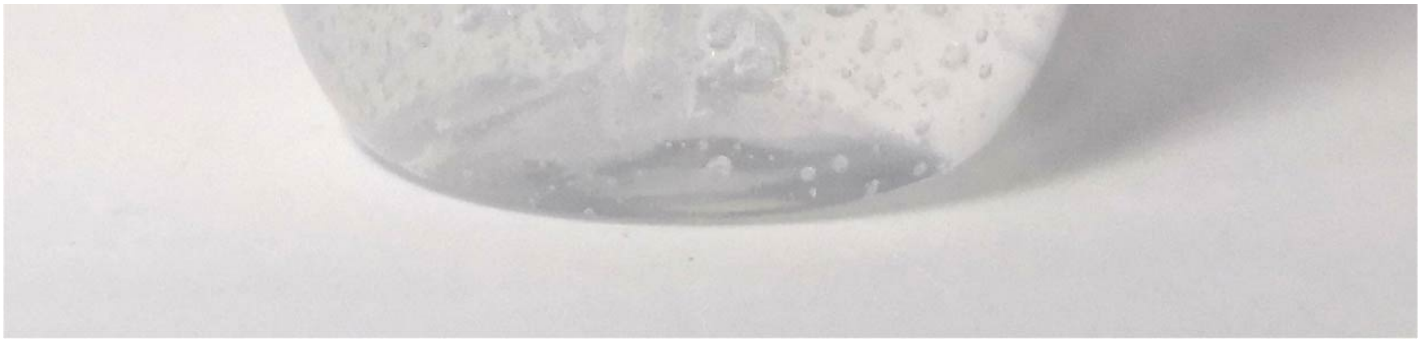
DIANJIE[®]

75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)



- EFFECTIVE STERILIZATION 99.9%
- DISPOSABLE ANTIBACTERIAL DISINFECTANT

NET CONTENT: 200 ML



Active ingredient[s]

Ethyl alcohol 75% v/v-----Antiseptic

Purpose

Use[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warning

**For external use only. Flammable.
Keep away from heat or flame.**

Do not use

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- 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.

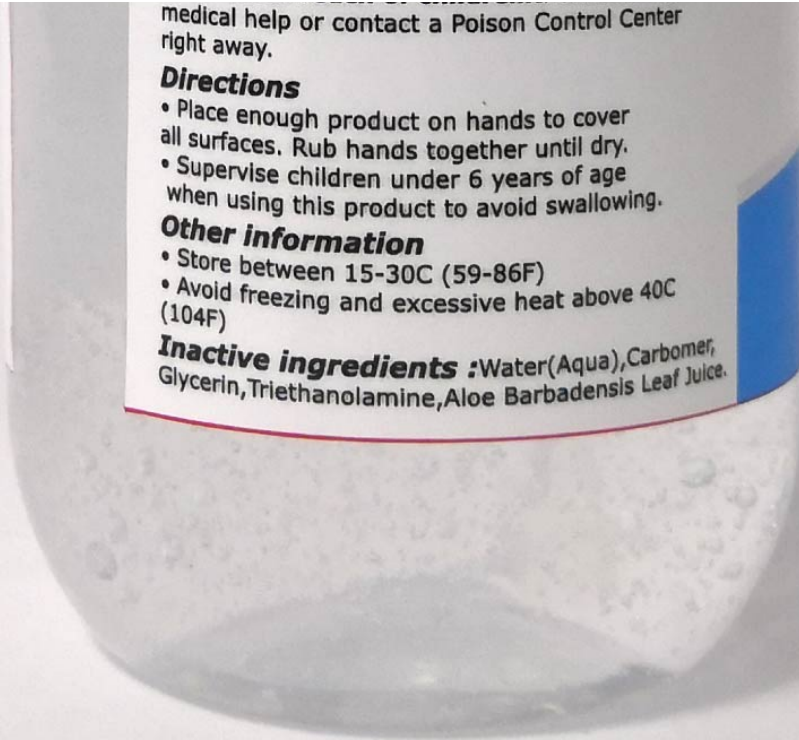
Directions

- 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 Barbadosis Leaf Juice.



Product Name : alcohol disinfectant
Brand :Dianjie
Specification : 200ML
Executive standard: Q / HZBOSS
005-2020
Health license No.: YWXZZ [2019] -
09-0004
Manufacturer: Boss(Huizhou)
Medical & Health Products Co., Ltd.
Production address: Baishida
Science and Technology Park,
Boluo County, Huizhou City,
Guangdong Province
Company website: www.bosshz.com
Validity: 2 years
Batch number and production date:
See the bottle .



250 mL NDC: 77313-975-15



DIANJIE[®]

75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)



- EFFECTIVE STERILIZATION 99.9%
- DISPOSABLE ANTIBACTERIAL DISINFECTANT

NET CONTENT: 250 ML

Active ingredient[s]

Ethyl alcohol 75% v/v-----Antiseptic

Purpose

Use[s]

Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warning

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.

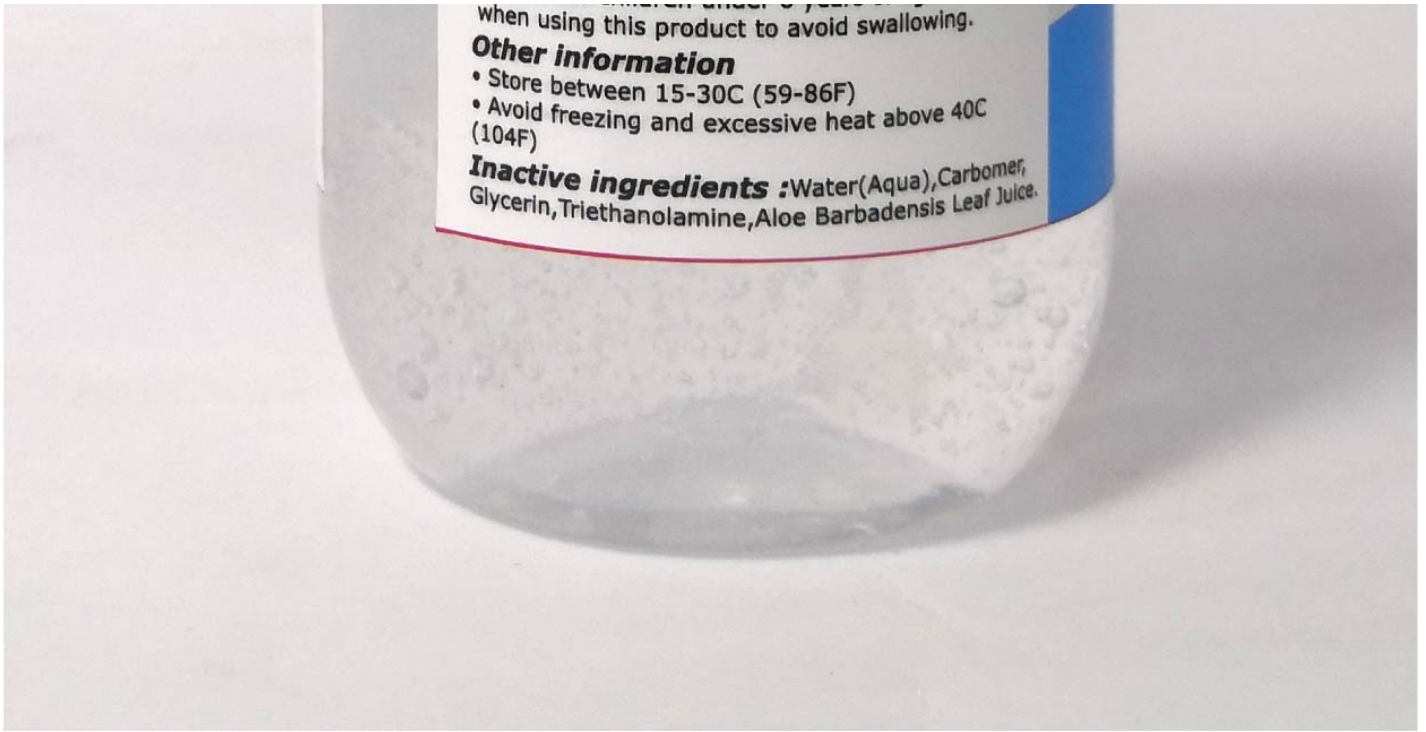
When using this product, keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

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



Executive standard: Q / HZBOSS
005-2020
Health license No.: YWXZZ [2019] -
09-0004
Manufacturer: Boss(Huizhou)
Medical & Health Products Co., Ltd.
Production address: Baishida
Science and Technology Park,
Boluo County, Huizhou City,
Guangdong Province
Company website: www.bosshz.com
Validity: 2 years
Batch number and production date:
See the bottle .



300 mL NDC: 77313-975-16



DIANJIE®

75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)



- EFFECTIVE STERILIZATION 99.9%
- DISPOSABLE ANTIBACTERIAL DISINFECTANT

NET CONTENT: 300 ML

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.

Warning

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Do not use

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- on open skin wounds.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

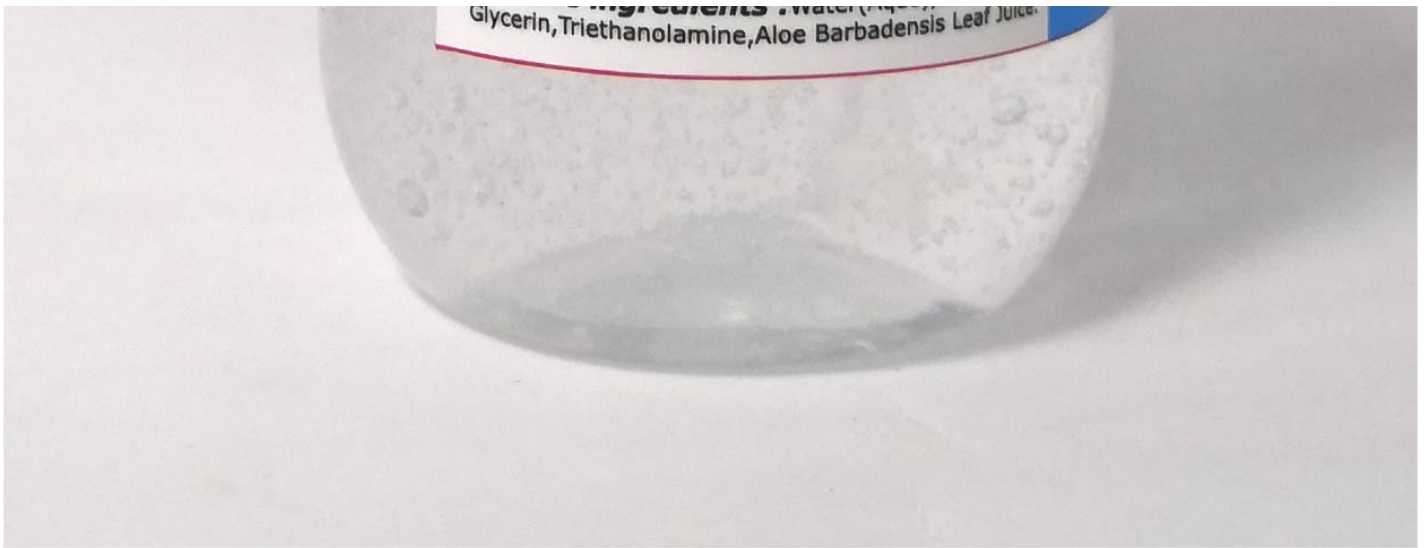
Directions

- 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,



350 mL NDC: 77313-975-17



75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)



- EFFECTIVE STERILIZATION 99.9%
- DISPOSABLE ANTIBACTERIAL DISINFECTANT

NET CONTENT: 350 ML



Active ingredient[s]

Ethyl alcohol 75% v/v-----Antiseptic

Purpose

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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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

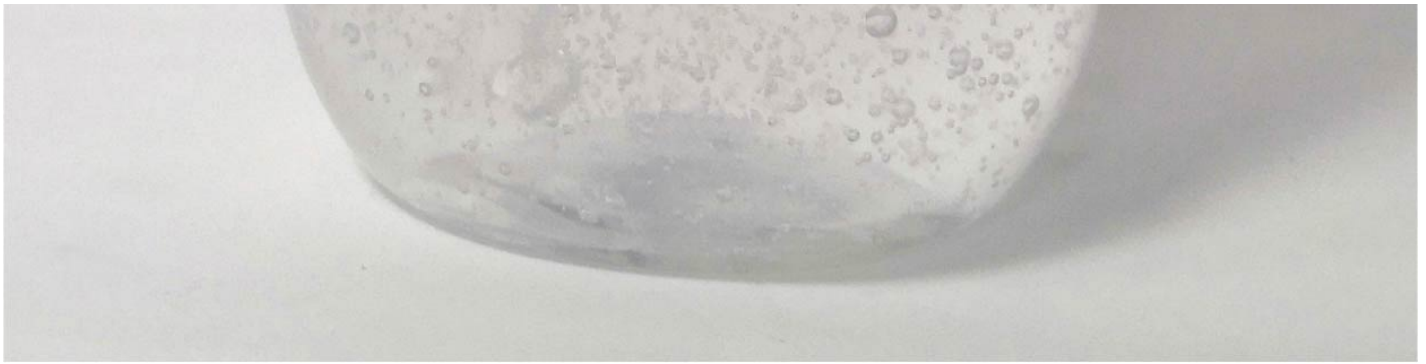
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

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

Product Name : alcohol disinfectant
Brand :Dianjie
Specification : 350ML
Executive standard: Q / HZBOSS
005-2020
Health license No.: YWXZZ [2019] -
09-0004
Manufacturer: Boss(Huizhou)
Medical & Health Products Co., Ltd.
Production address: Baishida
Science and Technology Park,
Boluo County, Huizhou City,
Guangdong Province
Company website: www.bosshz.com
Validity: 2 years
Batch number and production date:
See the bottle .



6 972037 881287



500 mL NDC: 77313-975-18





Active ingredient[s]

Ethyl alcohol 75% v/v-----Antiseptic

Purpose

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



Product Name : alcohol disinfectant
Brand :Dianjie

Specification : 500ML

Executive standard: Q / HZBOSS
005-2020

Health license No.: YWXZZ [2019] -
09-0004

Manufacturer: Boss(Huizhou)
Medical & Health Products Co., Ltd.

Production address: Baishida
Science and Technology Park,
Boluo County, Huizhou City,
Guangdong Province

Company website: www.bosshz.com

Validity: 2 years

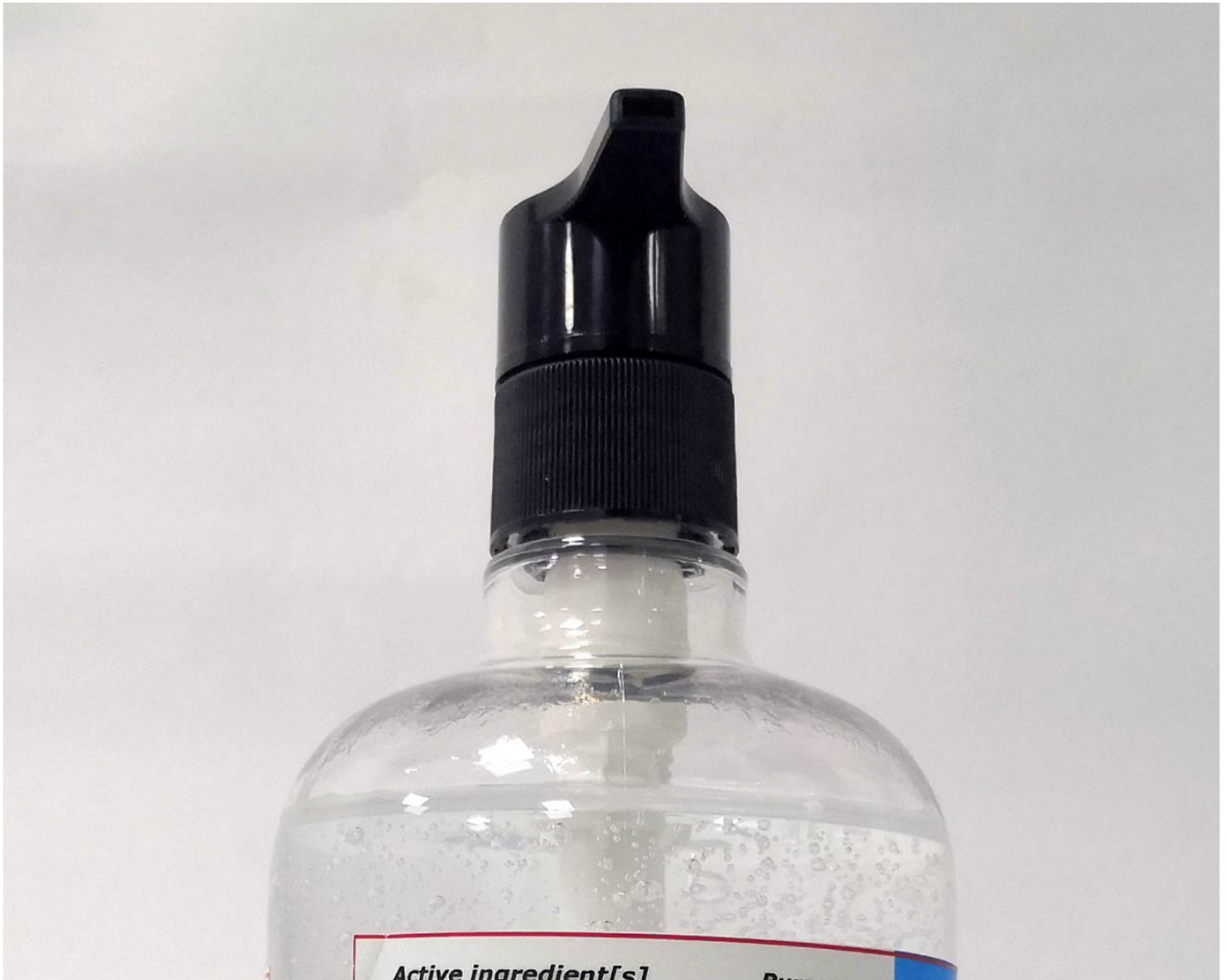
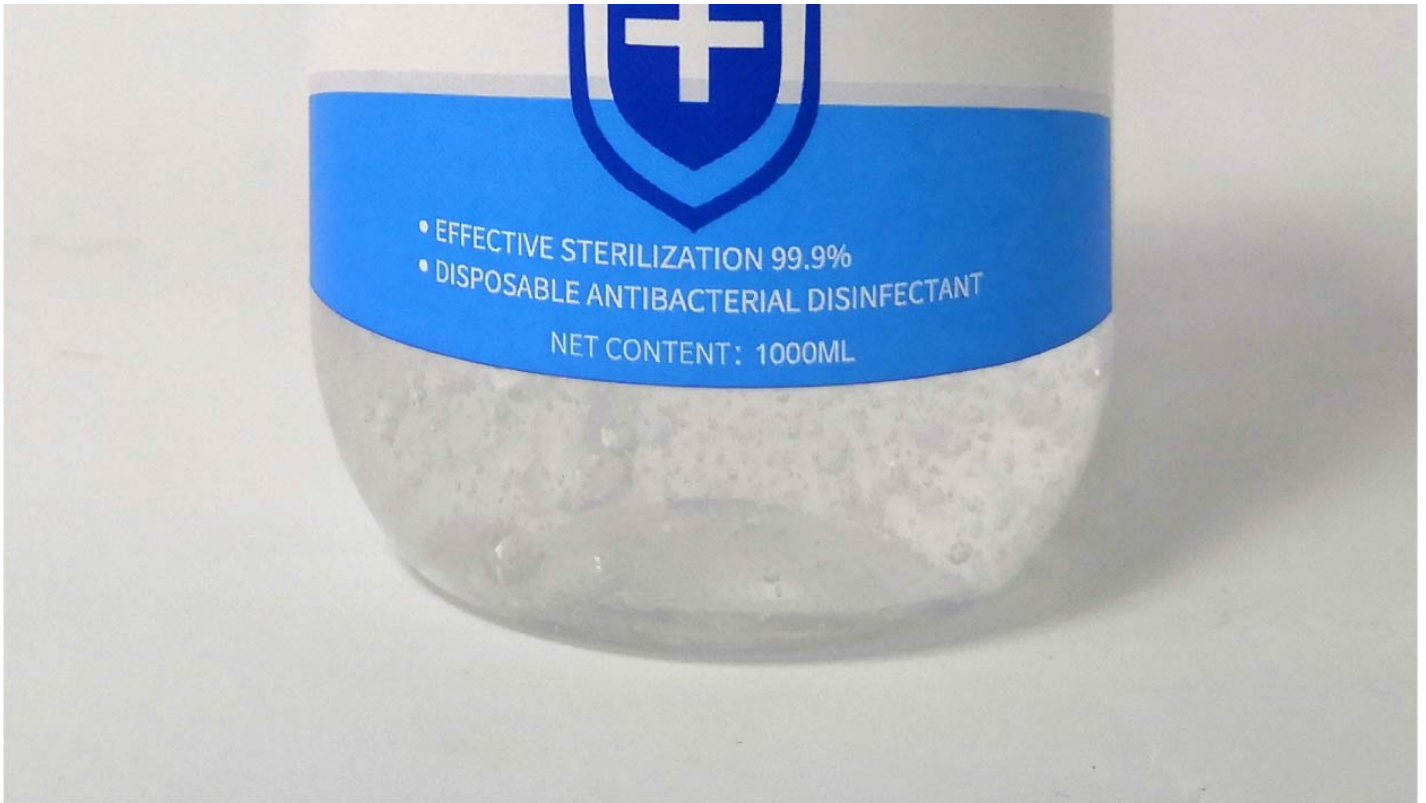
Batch number and production date:
See the bottle .



6 972037 881287

1000 mL NDC: 77313-975-19





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

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



Product Name : alcohol disinfectant
Brand :Dianjie

Specification : 1000ML

Executive standard: Q / HZBOSS
005-2020

Health license No.: YWXZZ [2019] -
09-0004

Manufacturer: Boss(Huizhou)
Medical & Health Products Co., Ltd.

Production address: Baishida
Science and Technology Park,
Boluo County, Huizhou City,
Guangdong Province

Company website: www.bosshz.com

Validity: 2 years

Batch number and production date:
See the bottle .



6 972037 881287

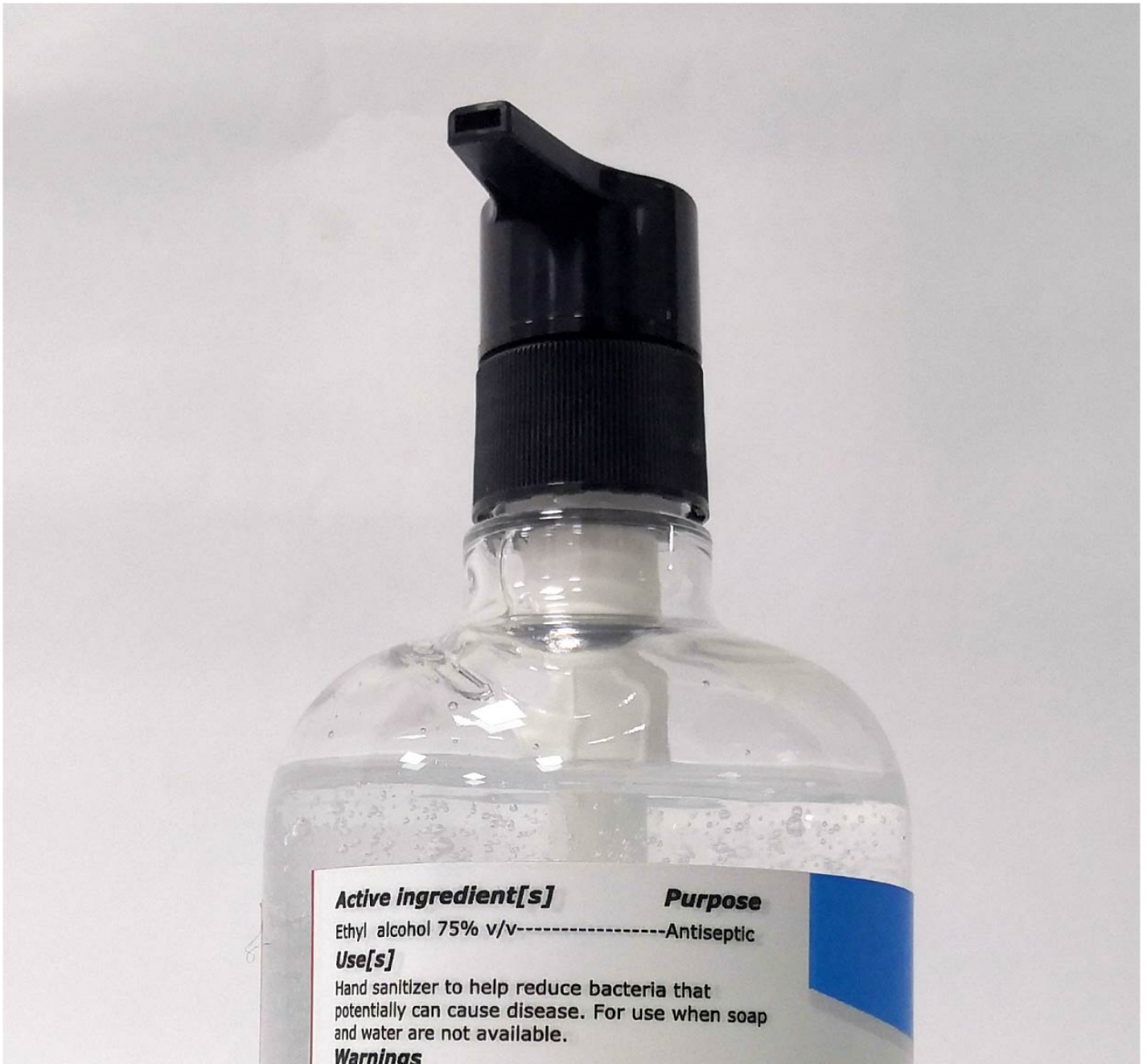
1500 mL NDC: 77313-975-20



DIANJIE[®]

75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)





For external use only. Flammable.
Keep away from heat or flame.

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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.



Product Name : alcohol disinfectant
Brand :Dianjie
Specification :1500ML
Executive standard: Q / HZBOSS
005-2020
Health license No.: YWXZZ [2019] -
09-0004
Manufacturer: Boss(Huizhou)
Medical & Health Products Co., Ltd.
Production address: Baishida
Science and Technology Park,
Boluo County, Huizhou City,
Guangdong Province
Company website: www.bosshz.com
Validity: 2 years
Batch number and production date:
See the bottle .



3785 mL NDC: 77313-975-21

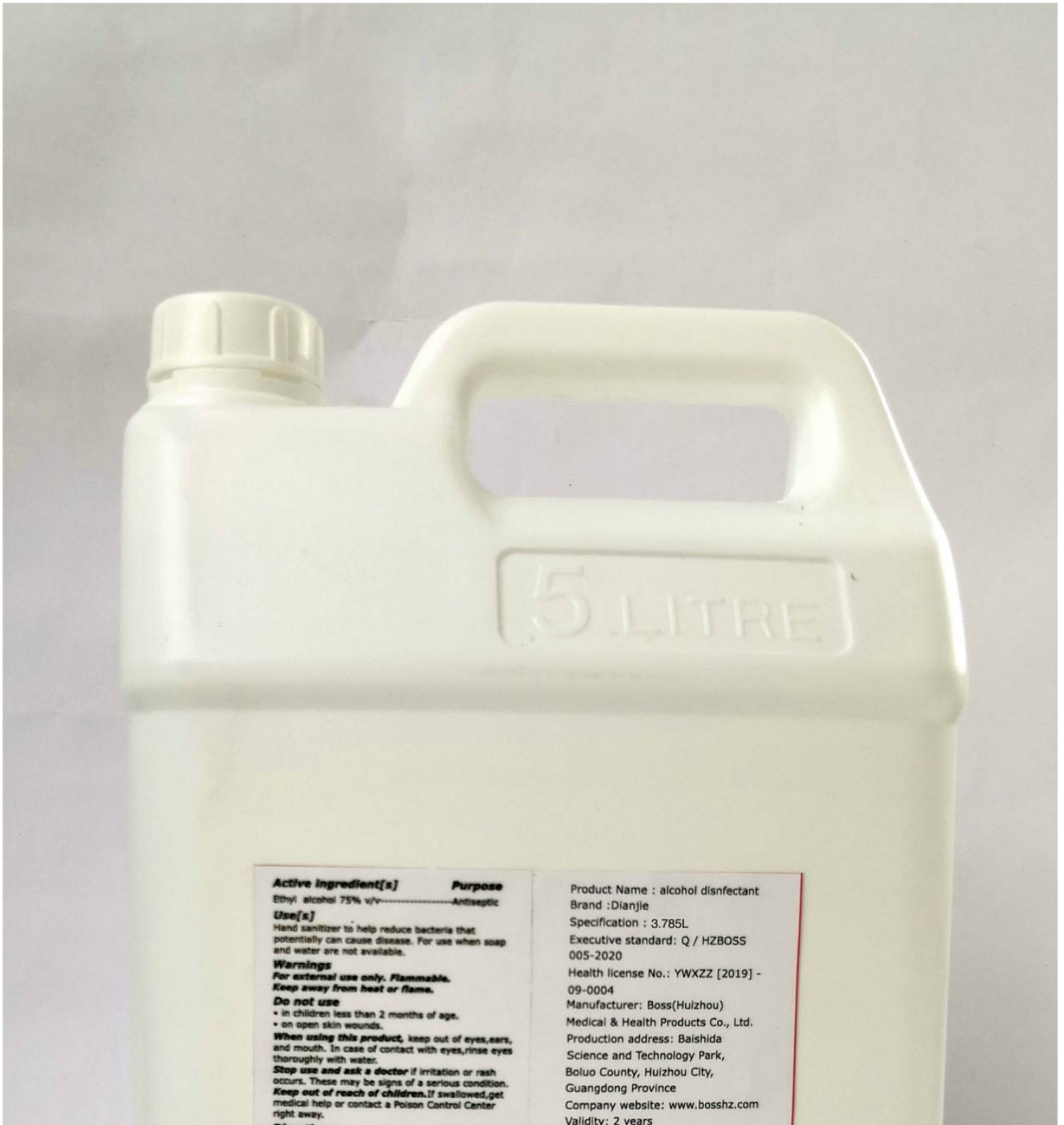
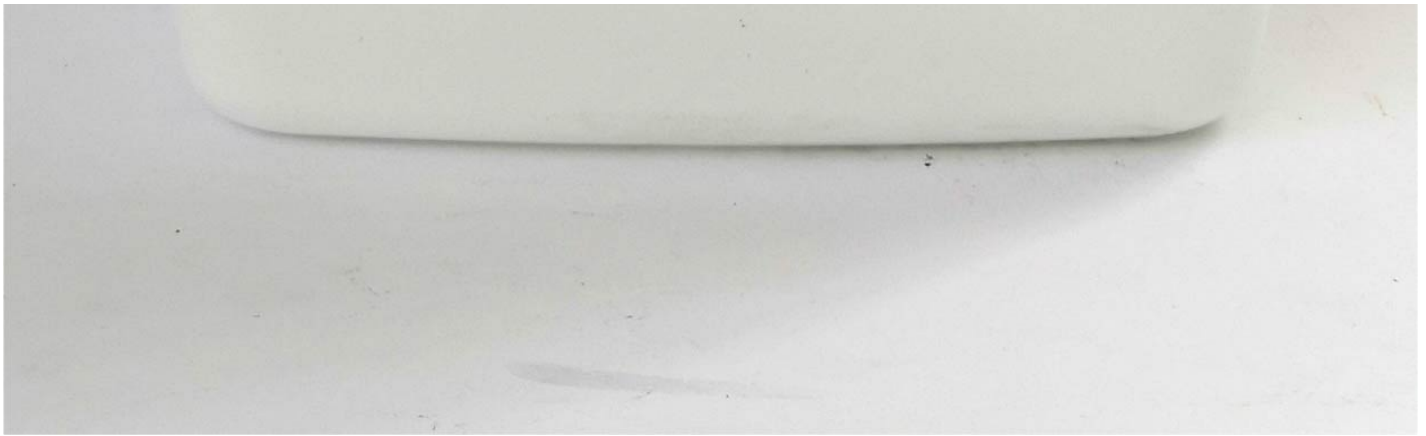
5 LITRE

DIANJIE[®]

75%ALCOHOL
DISINFECTANT
(DISPOSABLE GEL TYPE)



- EFFECTIVE STERILIZATION 99.9%
 - DISPOSABLE ANTIBACTERIAL DISINFECTANT
- NET CONTENT: 3.785L



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.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Product Name : alcohol disinfectant
Brand : Dianjie

Specification : 3.785L

Executive standard: Q / HZBOSS
005-2020

Health license No.: YWXZZ [2019] -
09-0004

Manufacturer: Boss(Hulzhou)
Medical & Health Products Co., Ltd.

Production address: Balshida
Science and Technology Park,
Boluo County, Hulzhou City,
Guangdong Province

Company website: www.bosshz.com

Validity: 2 years



HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77313-975
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
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.2 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.5 mL in 100 mL
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.3 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77313-975-13	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/14/2020	
2	NDC:77313-975-14	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/14/2020	
3	NDC:77313-975-15	250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/14/2020	
4	NDC:77313-975-16	300 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/14/2020	
5	NDC:77313-975-17	350 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/14/2020	
6	NDC:77313-975-18	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/14/2020	
7	NDC:77313-975-19	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/14/2020	
8	NDC:77313-975-20	1500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/14/2020	
9	NDC:77313-975-21	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/14/2020	
10	NDC:77313-975-11	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
11	NDC:77313-975-12	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/14/2020	

Labeler - Boss (Huizhou) Medical & Health Products Co., Ltd. (554530185)

Registrant - Hans Manufacturer Inc. (787300008)

Establishment

Name	Address	ID/FEI	Business Operations
Boss (Huizhou) Medical & Health Products Co., Ltd.		554530185	manufacture(77313-975) , pack(77313-975) , label(77313-975)

Revised: 5/2020

Boss (Huizhou) Medical & Health Products Co., Ltd.