

HAND SANITIZERS- hand sanitizers wipe cloth
WELLSOON TECHNOLOGY 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.

Active Ingredient(s)

Ethyl 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.

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

purified water USP, polyaminopropy biduanide

Package Label - Principal Display Panel



Alcohol Wipes

99.9%

kill 99.9% of germs

75% Alcohol
1PCS 6X8"(15.2X20.32cm)

Drug Facts

Active Ingredients

Ethyl Alcohol 75%

Purpose

Antiseptic

Use

For preparation of the skin prior to injection.

Warnings

- For external use only.
- Flammable, keep away from fire or flame.

Do Not Use

- with electrocautery procedures.
- If in the eyes contact occurs, flush eyes with water.

Stop Use

If irritation and redness develop. If condition continues, consult your health care practitioner.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wipe desired area and discard.

Other information

Store at room temperature 15° C-30° C(59° F-86° F)

Inactive Ingredients

purified water, benzalkonium chloride, polyaminopropyl biguanide

Manufactured by

WELLSOON TECHNOLOGY CO.,LTD

#34, Xin Ai Rd, South Dist. Tainan City, 70255, Taiwan

Contact : +886 6 265 3888 #32



4 1713435114792 4



NDC:78911-300-01

HAND SANITIZERS

hand sanitizers wipe cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78911-300
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	2.16 g in 2.88 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.003 g in 2.88 g

Inactive Ingredients

Ingredient Name	Strength
POLYAMINO PROPYL BIGUANIDE (UNII: DT9D8Z79ET)	0.097 g in 2.88 g
WATER (UNII: 059QF0K00R)	0.62 g in 2.88 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78911-300-01	2.88 g in 1 BAG; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2020	

Labeler - WELLSOON TECHNOLOGY CO., LTD (656811267)

Registrant - WELLSOON TECHNOLOGY CO., LTD (656811267)

Establishment

Name	Address	ID/FEI	Business Operations
WELLSOON TECHNOLOGY		656811267	manufacture(78911-300)

Revised: 7/2020

WELLSOON TECHNOLOGY CO., LTD