

HAND SANITIZER- alcohol gel
Davemed Healthcare 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.

Hand Sanitizer Davemed Healthcare Co., Ltd

Active Ingredient

Ethyl Alcohol 70% v/v

USES

To decrease bacteria on the skin that could cause disease.

Recommended for repeated use.

WARNING:

Flammable.

Keep away from fire or flame.

For external use of onlyh.

WHEN USING THIS PRODUCT:

avoid contact with eyes in case of eye contact immediately flush eyes with water, call a doctor avoid contact with broken skin.

STOP USE AND ASK A DOCTOR:

Discontinue use if irritation or redness develos, If condition persists from more than 72 hours, consult a doctor

KEEP OUT OF CHILDREN:

Children should only use this product under adult supervision

DIRECTIONS:

- Place enough product in your palm to thoroughly spread on both hands and rub into the skin undil dry
Recommended for repeated use.

INGREDIENTS:

Water, Alcohol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Peg-40, Hydrogenated Castor Oil, Parfum, Triethanolamine

Antiseptic

Do not drink. Not edible. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately

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



EFFECTIVE DISINFECTION
REACHED 99.9%

HAND SANITIZER



Net Wt: 60ml (2oz)

FOR EXTERNAL USE

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol 70% v/v	Antiseptic

Uses. hand sanitizer to help reduce bacteria on the skin recommended for repeated use.

Warnings • Flammable • Keep away from fire or flame
• For external use only

When using this product avoid contact with eyes in case of eye contact immediately flush eyes with water, call a doctor avoid contact with broken skin

Discontinue use if irritation or redness develops, If condition persists from more than 72 hours, consult a doctor

Keep out of reach of children. Children should only use this product under adult supervision

Do not drink. Not edible. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Other information • Store between 15-30° C • Avoid freezing and excessive heat above 40° C (104°F)

Directions • Place enough product in your palm to thoroughly spread on both hands and rub into the skin until dry Recommended for repeated use.

Inactive ingredients • Purified water, Acrylates/C10-30, Alkyl Acrylate Crosspolymer, Peg-40, Hydrogenated Castor Oil, Parfum, Triethanolamine

Manufacture in
Davemed Healthcare Co., Ltd
No. 150 Guomao Street, Jinhua, Zhejiang, China

Made in China

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70897-012
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
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0K00R)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	

TROLAMINE (UNII: 9O3K93S3TK)

PEG-40 SORBITAN DIISOSTEARATE (UNII: JL4CCU7IIG)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70897-012-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
2	NDC:70897-012-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
3	NDC:70897-012-03	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
4	NDC:70897-012-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
5	NDC:70897-012-05	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
6	NDC:70897-012-06	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
7	NDC:70897-012-07	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
8	NDC:70897-012-08	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
9	NDC:70897-012-09	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
10	NDC:70897-012-10	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
11	NDC:70897-012-11	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	
12	NDC:70897-012-12	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/30/2020	

Labeler - Davemed Healthcare Co., Ltd (529128716)

Establishment

Name	Address	ID/FEI	Business Operations
Davemed Healthcare Co., Ltd		529128716	manufacture(70897-012)

Revised: 7/2020

Davemed Healthcare Co., Ltd