INSTANT HAND SANITIZER 70% ALCOHOL- alcohol liquid
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.

Instant Hand Santizer

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 United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, 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 (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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 irrittion or redness develops. If condition persists for 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.

Directions

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

Other information

- Do not store above 105F
- May discolor some fabrics.
- Harmful to wood finishes and plastics

Inactive ingredients

aloe bardensis leaf extract, caprylyl glycol carbomer, glycerin, isopropyl alcohol, isopropyl myristate, hydrochloric acid, sodium chloride

Package Label - Principal Display Panel

INSTANT HAND SANITIZER 70% ALCOHOL

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70897-009
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**
HYDROCHLORIC ACID (UNII: QTT17582CB)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70897-009-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:70897-009-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:70897-009-03	80 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:70897-009-04	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:70897-009-05	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
6	NDC:70897-009-06	300 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
7	NDC:70897-009-07	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
8	NDC:70897-009-08	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
9	NDC:70897-009-09	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
10	NDC:70897-009-10	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333A	03/30/2020	

Labeler - Davemed Healthcare Co., Ltd (529128716)

Establishment

Name	Address	ID/FEI	Business Operations
Davemed Healthcare Co., Ltd		529128716	manufacture(70897-009)

Revised: 7/2020 Davemed Healthcare Co., Ltd