

HAND SANITIZER GEL- hand sanitizer gel gel
Dongyang Medical & Hygienic Articles 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.

81276-017 1L HAND SANITIZER GEL DONGYANG MEDICAL

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

POLYACRYLIC ACID , AMINOMETHYLPROPANOL ,PROPYLENE GLYCOL, GLYCERIN ,

WATER

Package Label - Principal Display Panel

1 L NDC: 81276 -017-01



HAND SANITIZER GEL				
hand sanitizer gel gel				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:8 1276-0 17	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	750 mL in 1 L	
Inactive Ingredients				
	Ingredient Name		Strength	
	GLYCERIN (UNII: PDC6A3C0OX)			
	AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			
	WATER (UNII: 059QF0K00R)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:8 1276-017-01	1 L 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 - Dongyang Medical & Hygienic Articles Co., Ltd. (530310429)

Registrant - Dongyang Medical & Hygienic Articles Co., Ltd. (530310429)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Dongyang Medical & Hygienic Articles Co., Ltd.		530310429	manufacture(81276-017)

Revised: 12/2020

Dongyang Medical & Hygienic Articles Co., Ltd.