

INSTANT HAND SANITIZER- instant hand sanitizer liquid
Zhejiang 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.

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 DENAT. 70%

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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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

AQUA, Propylene Glycol, Glycerin, CARBOMER, AMINOMETHYL PROPANOL

Package Label - Principal Display Panel

560ml



INSTANT HAND SANITIZER

Active ingredient	Purpose
Ethyl alcohol 70%	Antiseptic

Uses • to decrease bacteria on the skin that could cause disease
• recommended for repeated use.

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

When using this product • keep out of eyes. In case of contact with eyes, flush thoroughly with water. • avoid contact with broken skin • do not inhale or ingest.

Stop use and ask a doctor if • irritation or redness develops • condition persists for more than 72 hours.

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

Inactive ingredients purified water, propylene glycol, glycerin, carbomer, aminomethyl propanol.

Sanitary License: ZWXZZ (2020) NO. 0065 Executive Standard: GB26373-2010

Manufacturer: Dongyang Medical & Hygienic Articles Co., Ltd.

Add: Liushi Industrial Zone, Liushi Street, Dongyang City, Jinhua City, Zhejiang Province, China.

PRO: 2020/03/28 EXP: 2022/03/27



MADE IN CHINA
REF: HS2020-2



INSTANT HAND SANITIZER

instant hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53031-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	392 mL in 560 mL

Inactive Ingredients

Ingredient Name	Strength
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	DureSafety
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53031-010-01	560 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Zhejiang Dongyang Medical & Hygienic Articles Co., Ltd. (530310429)**Establishment**

Name	Address	ID/FEI	Business Operations
Zhejiang Dongyang Medical & Hygienic Articles Co., Ltd.		530310429	manufacture(53031-010)

Revised: 5/2020

Zhejiang Dongyang Medical & Hygienic Articles Co., Ltd.