

HAND SANITIZER- hand sanitizer gel
ZHEJIANG SHUNAN INDUSTRY&TRADE 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.

75556-009 473ml 62.5%

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 62.5% 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

WATER(AQUA), GLYCERIN, FRAGRANCE/PARFUM, CARBOMER,AMINOMETHYL PROPANOL, PROPANEDIOL,SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL , ALOE BARBADENSIS (ALOE VERA) LEAF JUICE , PROPYLENE GLYCOL, TOCOPHERYL ACETATE , HELIANTHUS ANNUUS (SUNFLOWER)SEED OIL, ACTINIDIA CHINENSIS (KIWI) FRUIT EXTRACT, FRAGARIA CHILOENSIS (STRAWBERRY) FRUIT EXTRACT ,PUNICA GRANATUM (POMEGRANATE) FRUIT EXTRACT, VACCINIUM ANGUSTIFOLIUM [BLUEBERRY]FRUIT EXTRACT, VACCINIUM MACROCARPON (CRANBERRY) FRUIT EXTRACT

Package Label - Principal Display Panel

473 mL in 1 bottle NDC: 75556-009-01



artnaturals® HAND SANITIZER, FORMULATED WITH 62.5% ALCOHOL, AND INFUSED WITH ALOE VERA AND JOJOBA, IS AN EFFECTIVE SOLUTION TO HELP KEEP HANDS HYGENIC & HYDRATED.

DIST. BY artnaturals®
Gardena, CA 90248
artnaturals.com
info@artnaturals.com
Customer service:
855-ART-4488



100291802024



Manufacture Date: 06/28/2020
Best if used by: 06/27/2023
Lot No. 01937
MADE IN CHINA



hand sanitizer

HAND SANITIZER

NATURAL ELEMENTS
+ CLEANSING FORMULA

INFUSED WITH JOJOBA OIL

16 fl oz (473 ml)

DRUG FACTS	
ACTIVE INGREDIENTS: ETHYL ALCOHOL 62.5%	PURPOSE: ANTISEPTIC
USES: HAND SANITIZER CAN 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: <ul style="list-style-type: none">• 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.	
DIRECTIONS: <ul style="list-style-type: none">• 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 INFO: <ul style="list-style-type: none">• STORE BETWEEN 15-30C (59-86F)• AVOID FREEZING AND EXCESSIVE HEAT ABOVE 40C (104F)	
INACTIVE INGREDIENTS: WATER (AQUA), GLYCERIN, FRAGRANCE / PARFUM, CARBOMER, AMINOMETHYL PROPANOL, PROPANEDIOL, SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL, ALOE BARBADENSIS (ALOE VERA) LEAF JUICE, PROPYLENE GLYCOL, TOCOPHERYL ACETATE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, ACTINIDIA CHINENSIS (KIWI) FRUIT EXTRACT, FRAGARIA CHILOENSIS (STRAWBERRY) FRUIT EXTRACT, PUNICA GRANATUM (POMEGRANATE) FRUIT EXTRACT, VACCINIUM ANGUSTIFOLIUM (BLUEBERRY) FRUIT EXTRACT, VACCINIUM MACROCARPON (CRANBERRY) FRUIT EXTRACT.	

HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75556-009
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	295.625 mL in 473 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CRANBERRY JUICE (UNII: Y74M3X3345)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
KIWI FRUIT (UNII: 71ES77LGJC)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPANEDIOL (UNII: 5965N8W85T)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
JOJOBA OIL (UNII: 724GKU717M)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
STRAWBERRY JUICE (UNII: U8NS58UGW0)	
POMEGRANATE JUICE (UNII: 99S671U9KB)	
LOWBUSH BLUEBERRY JUICE (UNII: 834067J0NY)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	artnaturals
Contains			

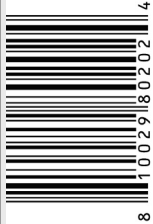
Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75556-009-01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	



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36M

 Manufacture Date: 06/28/2020
 Best if used by: 06/27/2023
 Lot No. 01937
 MADE IN CHINA

hand sanitizer

 HAND SANITIZER
 NATURAL ELEMENTS
 + CLEANSING FORMULA
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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 SHUNAN INDUSTRY & TRADE CO., LTD (528198838)

Registrant - ZHEJIANG SHUNAN INDUSTRY & TRADE CO., LTD (528198838)

Establishment

Name	Address	ID/FEI	Business Operations
ZHEJIANG SHUNAN INDUSTRY & TRADE CO., LTD		528198838	manufacture(75556-009)

Revised: 6/2020

ZHEJIANG SHUNAN INDUSTRY & TRADE CO., LTD