

SANITFRESH ANTISEPTIC HAND SANITIZER 8OZ- alcohol gel
SANITFRESH ANTISEPTIC HAND SANITIZER 1 GALLON- alcohol gel
Wormser Corporation

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 72% 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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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

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Water, Carbomer, Aminomethyl Propanol, Butylene Glycol, Glycerin, Aloe Barbadensis Leaf Juice, Isopropyl Myristate, Ethyl Hexanediol, Phenoxyethanol

Package Label - Principal Display Panel

Drug Facts	
Active Ingredient	Purpose
Alcohol 72%	Antiseptic
Use(s)	
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	
<ul style="list-style-type: none"> ▪ on 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 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 Information	
<ul style="list-style-type: none"> ▪ Store between 15-30C (59-86F) ▪ Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients: Water (Aqua), Carbomer, Aminomethyl Propanol, Butylene Glycol, Glycerin, Aloe Barbardensis Leaf Juice, Isopropyl Myristate, Ethyl Hexanediol, Phenoxethanol.	
Questions? 800-666-9676	

Made in USA with USA and Globally Sourced Materials
Distributed by Wormser Corporation
Englewood, NJ 07631



ANTISEPTIC
hand sanitizer
72% ALCOHOL

KILLS 99.99% OF GERMS

With Natural Aloe Vera and Glycerin to Moisturize
Fragrance Free
8 fl. oz. (236 mL)



SanitFresh leaves your hands feeling fresh and sanitized without the need for soap and water. Our fast-drying, no-rinse, antiseptic hand sanitizer kills 99.99% of most germs and bacteria. Fragrance free, moisturizing formula has added natural Aloe Vera and Glycerin to leave skin feeling soft and smooth.



Customer: **WORMSER**
Folder: **WORMSER•13-68•artwork**
File: **SanitFresh_8ozHandSanitizerLabel_A_V.ai**
ITEM#: **TBD** PRECISION#: **TBD**
SIZE: **4.5" x 6.125" w/.125" cr**
JOB#: **TBD**
UNWIND: **TBD**
SUBSTRATE: **TBD**
DATE: **5/29/2020**

PREPARED BY: **SS**
PROOF #: **1**

Color Guide:

- dieline does not print
- deco area does not print
- PMS 2905
- PMS 2925
- PMS 3395
- PMS 432



50 Marcus Blvd.
Hauppauge, NY 11788
tel 631.293.4200
fax 631.293.4203

IMPORTANT: Please review proof for typographical errors, format, style and color breaks. This is a representation of the desired color. Please reference PANTONE® color guide for a more accurate color.

PLEASE NOTE: Before proceeding, all proofs and revised proofs MUST be signed and returned.

Approved **Not Approved**

236 mL NDC: 78512-001-00

Package Label Principal Display Panel



ANTISEPTIC
hand
sanitizer
72% ALCOHOL

KILLS 99.99% MOST OF GERMS
With Natural Aloe Vera and Glycerin to Moisturize
Fragrance Free

1 GALLON (128 FL. OZ.)

SanitFresh leaves your hands feeling fresh and sanitized without the need for soap and water. Our fast-drying, no-rinse, antiseptic hand sanitizer kills 99.99% of most germs and bacteria. Fragrance free, moisturizing formula has added natural Aloe Vera and Glycerin to leave skin feeling soft and smooth.

Drug Facts	
Active Ingredient	Purpose
Alcohol 72%	Antiseptic
Uses(s)	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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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 information	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	
Inactive ingredients: Water (Aqua), Carbomer, Aminomethyl Propanol, Butylene Glycol, Glycerin, Aloe Barbadensis Leaf Juice, Isopropyl Myristate, Ethyl Hexanediol, Phenoxyethanol.	
Questions? 800-886-8876	

Made in USA with USA and Globally Sourced Materials
Distributed by: Womeer Corporation Englewood, NJ 07631

NOT FOR RESALE

4.25"

6.75"

SANITFRESH ANTISEPTIC HAND SANITIZER 8OZ

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78512-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.001 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.01 mL in 100 mL

WATER (UNII: 059QF0KO0R)	27.65597 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06303 mL in 100 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0098 mL in 100 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.25 mL in 100 mL
ETHOHEXADIOL (UNII: M9JGK7U88V)	0.00015 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.00005 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78512-001-00	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/08/2020	

SANITFRESH ANTISEPTIC HAND SANITIZER 1 GALLON

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78512-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.001 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.01 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27.65597 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06303 mL in 100 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0098 mL in 100 mL
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.25 mL in 100 mL
ETHOHEXADIOL (UNII: M9JGK7U88V)	0.00015 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.00005 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78512-002-00	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/15/2021	

Labeler - Wormser Corporation (150857043)

Registrant - Nu-World Corporation (628045858)

Establishment

Name	Address	ID/FEI	Business Operations
Nu-World Corporation		628045858	manufacture(78512-001, 78512-002)

Revised: 2/2021

Wormser Corporation