GILWAY ANTISEPTIC HAND SANIIZER 3.8L- alcohol gel
GILWAY ANTISEPTIC HAND SANIIZER 8 FL.OZ- alcohol gel
Rema Foods, Inc.

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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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.

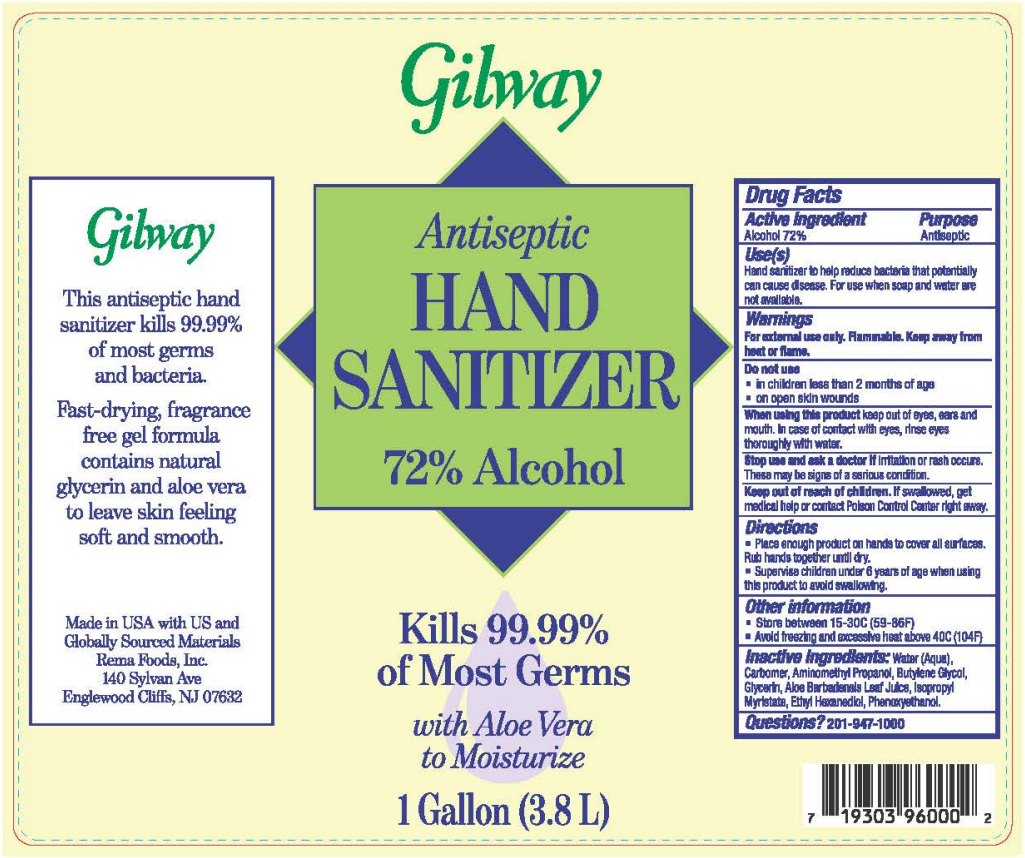
Other information

- 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



Customer: **WORMSER**
Folder: **WORMSER•13-66•artwork**
File: **Gilway_128oz_HandSanitizerLabel_Aloe_V.ai**
SYSPRO#: **TBD** PRECISION#: **TBD**
SIZE: **5" x 6" w/.125" cr**
JOB#: **TBD**
UNWIND: **TBD**
SUBSTRATE: **TBD** PREPARED BY: **JR**
DATE: **5/20/2020** PROOF #: **1**

Color Guide:
- dieline does not print
- deco area does not print
- PMS 387 @ 30%
- PMS 367
- PMS 355
- PMS Blue 072
- Black

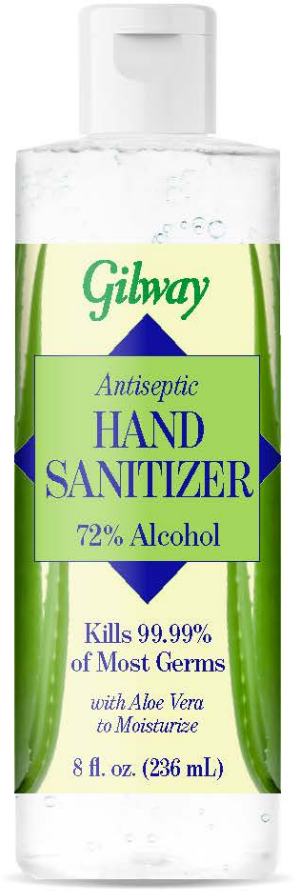
PRECISION LABEL CORPORATION
50 Marcus Blvd.
Hauppauge, NY 11788
tel 631.293.4200
fax 631.293.4203

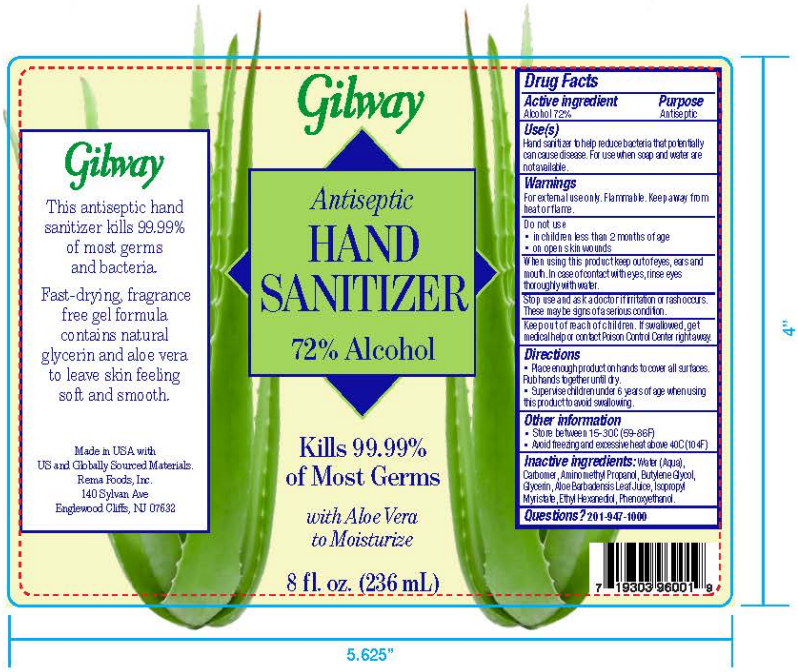
IMPORTANT: Please review proof for typographical errors, format, style and color breaks. This is a representation of the desired color. Please reference PANTONE® color guide for a more accurate color.

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

☐ Approved ☐ Not Approved

Package Label. Principal Display Panel-8 fl.oz





05.14.20 8oz HAND SANITIZER LABEL NW FORMULA	WORMSER
DIELINE PRINTABLE AREA 4/C PROCESS WHITE VINYL	WORMSER CORPORATION 150 Coolidge Avenue Englewood, NJ 07631 201-627-1000 www.wormsercorp.com

8 fl.oz(236 ml), NDC: 78230-002

GILWAY ANTISEPTIC HAND SANIIZER 3.8L

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:78230-001
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**
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	0.25 mL in 100 mL

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL
ETHOHEXADIOL (UNII: M9JGK7U88V)	0.00015 mL in 100 mL
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.001 mL in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.00005 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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0098 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78230-001-00	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/20/2020	

GILWAY ANTISEPTIC HAND SANIIZER 8 FL.OZ

alcohol gel

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78230-002-00	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/01/2020	

Labeler - Rema Foods, Inc. (194278768)

Registrant - Nu-World Corporation (628045858)

Establishment

Name	Address	ID/FEI	Business Operations
Nu-World Corporation		628045858	manufacture(78230-001, 78230-002)

Revised: 8/2020 Rema Foods, Inc.