# COMES IN HANDY BY JULEP ANTIBACTERIAL HAND SANITIZER- alcohol gel COMES IN HANDY BY JULEP ANTIBACTERIAL HAND 24OZSANITIZER- alcohol gel Nu-World 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.

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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 8OZ



NDC:68577-001-00

Package Label-Principal Display Panel 24OZ



24OZ NDC: 68577-002-00

#### COMES IN HANDY BY IIII EP ANTIBACTERIAL HAND SANITIZER

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llcohol gel					
Product Information					
Product Type	HUMAN OTC DRUG	Item Code	(Source)	ND	C:68577-001
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
In	gredient Name		Basis of Streng	gth	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCO			ALCOHOL		72 mL in 100 mL
Inactive Ingredients					
	Ingredient Name				Strength
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)			0.0	001 mL	in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)			0.00005 mL in 100 mL		
CARBOMER HOMOPOLYMER,	UNSPECIFIED TYPE (UNII: 0 A5MM	307FC)	0.2	25 mL	in 100 mL

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL
ETHOHEXADIOL (UNII: M9JGK7U88V)	0.00015 mL in 100 mL
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06303 mL in 100 mL
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.0098 mL in 100 mL
GLYCERIN (UNII: PDC6 A3C0 OX)	0.01 mL in 100 mL
WATER (UNII: 059QF0KO0R)	27.65597 mL in 100 mL

l	Packaging			
l	# Item Cod	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:68577-00	-00 236 mL in 1 BOTTLE; Type 0: Not a Combination I	roduct 04/24/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/24/2020	

## COMES IN HANDY BY JULEP ANTIBACTERIAL HAND 24OZSANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68577-002
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety		
ı	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

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Ingredient Name	Strength			
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CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	0.25 mL in 100 mL			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL			
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WATER (UNII: 059QF0KO0R)	27.65597 mL in 100 mL			

ı	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date

1 NDC:68577-002-00 7	709 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	
M. J.C.			
Marketing Info	rmation		
Marketing Category	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not fina	al part333A	05/01/2020	

### Labeler - Nu-World Corporation (628045858)

### Registrant - Nu-World Corporation (628045858)

Establishment			
Name	Address	ID/FEI	Business Operations
Nu-World Corporation		628045858	manufacture(68577-001, 68577-002)

Revised: 5/2020 Nu-World Corporation