BEAUTY SECRETS ANTISEPTIC HAND SANITIZER 20Z- alcohol gel BEAUTY SECRETS ANTISEPTIC HAND SANITIZER 80Z- alcohol gel Arcadia Beauty Labs LLC

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)

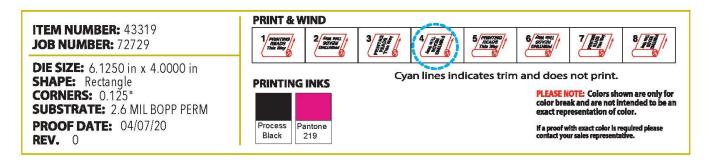
Inactive ingredients

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

8oz Package Label - Principal Display Panel

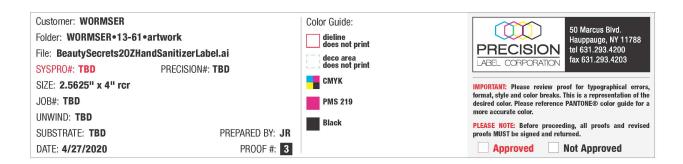
PROOF





236 mL NDC: 71990-001-00





BEAUTY SECRETS ANTISEPTIC HAND SANITIZER 20Z

alcohol gel

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Product	Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71990-002

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients			
Ingredient Name	Strength		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06303 mL in 100 mL		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	0.001 mL in 100 mL		
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)	0.00005 mL in 100 mL		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.0098 mL in 100 mL		
ETHOHEXADIOL (UNII: M9JGK7U88V)	0.00015 mL in 100 mL		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	0.25 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX)	0.01 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	27.65597 mL in 100 mL		

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:71990-002-00	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

BEAUTY SECRETS ANTISEPTIC HAND SANITIZER 80Z

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71990-003
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		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	$0.06303\;mL$ in $100\;mL$		
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	0.001mL in $100mL$		
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.00005mL in $100mL$		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	0.25 mL in 100 mL		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.0098 mL in 100 mL		
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WATER (UNII: 059QF0KO0R)	27.65597 mL in 100 mL		

l	P	ackaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:71990-003-00	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/01/2020	

Labeler - Arcadia Beauty Labs LLC (078445217)

Registrant - Nu-World Corporation (628045858)

Establishment				
Name	Address	ID/FEI	Business Operations	
Nu-World Corporation		628045858	manufacture(71990-002, 71990-003)	

Revised: 5/2020 Arcadia Beauty Labs LLC