SANXIDERM ANTI-BACTERIAL HAND GEL 8OZ- alcohol gel SANZIDERM ANTISEPTIC HAND SANITIZER 8OZ- alcohol gel Beauty Partners 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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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

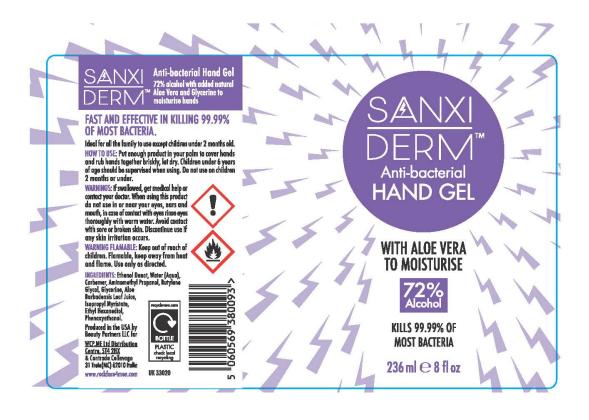
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

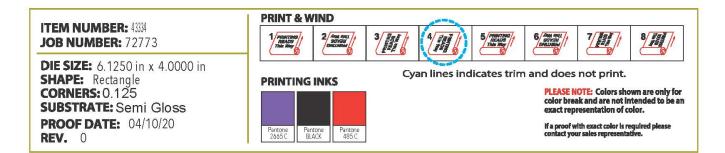
Inactive ingredients

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

Package Label - Principal Display Panel-SANXIDERM Anti-bacterial Hand Gel

PROOF

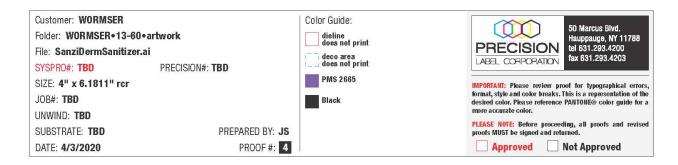




236mL NDC: 78229-001-00

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL-SANZIDERM Antiseptic Hand Sanitizer 8OZ





SANXIDERM ANTI-BACTERIAL HAND GEL 8OZ

alcohol gel

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Product	Intor	mation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:78229-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

п	8		
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			
GLYCERIN (UNII: PDC6A3C0OX)	0.01 mL in 100 mL			
WATER (UNII: 059QF0KO0R)	27.65597 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			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL			
ALOE VERA LEAF (UNII: ZY81Z83H0 X)	0.0098 mL in 100 mL			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	0.001 mL in 100 mL			
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.00005 mL in 100 mL			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06303 mL in 100 mL			

	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
П	1 NDC:78229-001-00	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	

SANZIDERM ANTISEPTIC HAND SANITIZER 80Z

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78229-002
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			
GLYCERIN (UNII: PDC6A3C0OX)	0.01 mL in 100 mL			
WATER (UNII: 059QF0KO0R)	27.65597 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			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	0.01 mL in 100 mL			
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0098 mL in 100 mL			
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	0.001mL in $100mL$			
PHENOXYETHANOL (UNII: HIE492ZZ3T)	$0.00005\;mL$ in $100\;mL$			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	0.06303 mL in 100 mL			

ı	Pac	kaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 N	DC:78229-002-00	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	

Labeler - Beauty Partners LLC (080320170)

Registrant - Nu-World Corporation (628045858)

Establishment				
Name	Address	ID/FEI	Business Operations	
Nu-World Corporation		628045858	manufacture(78229-001, 78229-002)	

Revised: 6/2020 Beauty Partners LLC