HAND SANITIZER- alcohol gel
Au Natural Organics Company

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.

AU NATURAL ORGANICS HAND SANITIZER GEL
alcohol gel

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.

Purpose

Antiseptic, Hand Sanitizer

Warnings

For external use only. Flammable. Keep away from heat or flame

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

glycerin, hydrosol, rosemary oil, citrus reticulata seed oil, lemon oil, aloe, konjac , plant coloring, zinc sulfate,

alcohol 75%, antiseptic

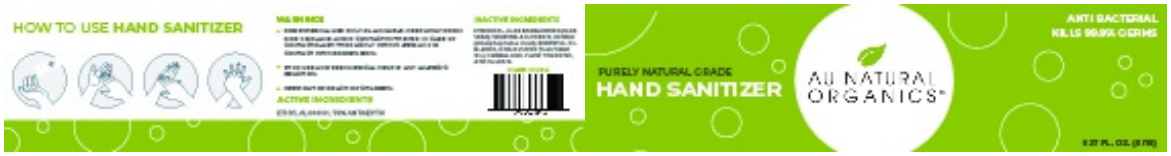
Use an alcohol-based hand sanitizer that contains at least 60% alcohol. Supervise young children when they use hand sanitizer to prevent swallowing alcohol.

Put enough sanitizer on your hands to cover all surfaces.
Rub your hands together until they feel dry (this should take around 20 seconds).

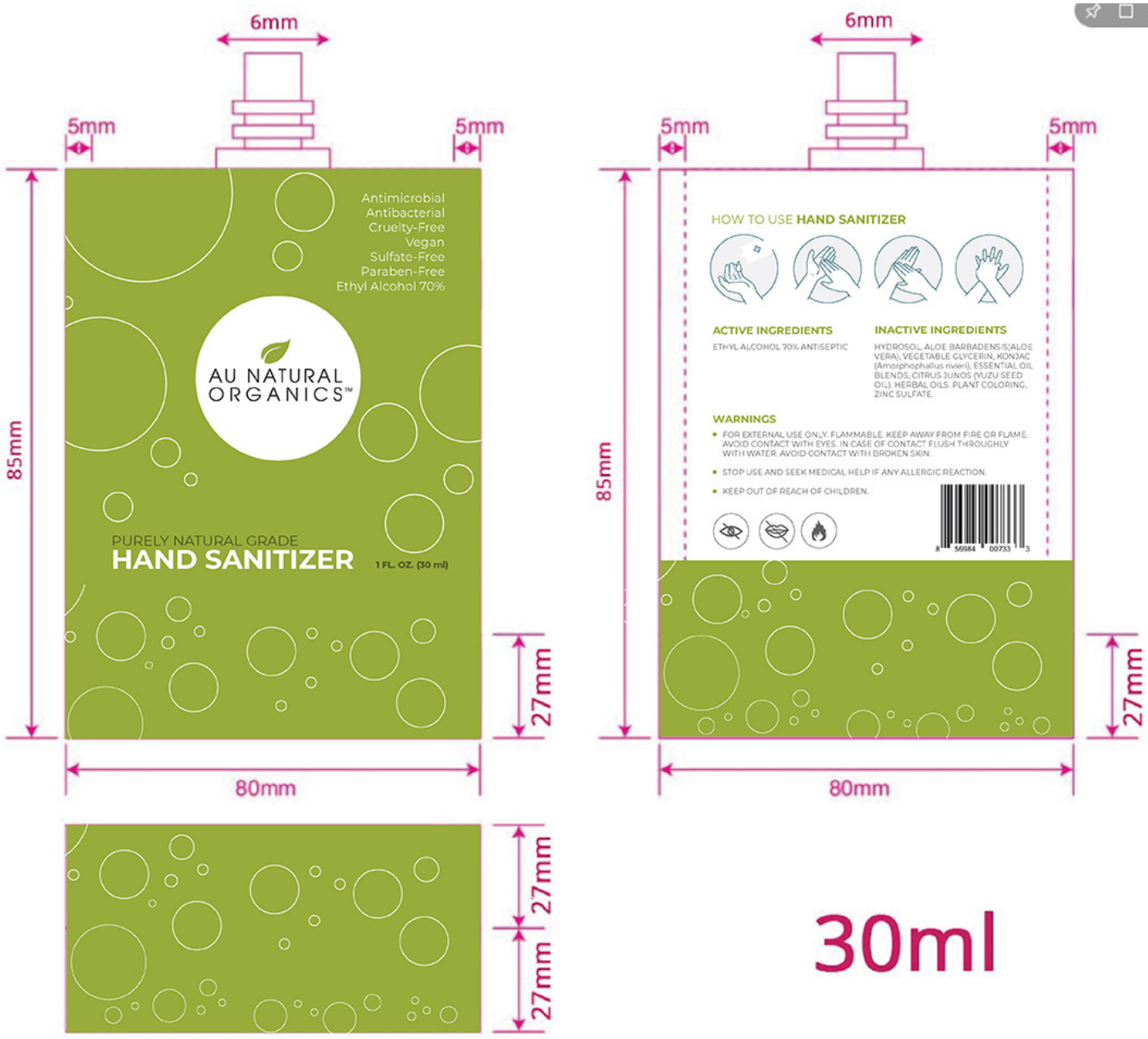
Do NOT rinse or wipe off the hand sanitizer before it's dry; it may not work well against germs.

Package Label - Principal Display Panel

5mL NDC: 79297-020-05



30mL NDC: 79297-020-01



HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79297-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRUS RETICULATA FRUIT OIL (UNII: 25P9H3QU5E)	
AMORPHOPHALLUS KONJAC FLOWER/STEM/TUBER (UNII: QW0X0GJK24)	
ALOE (UNII: V5VD430YW9)	
GLYCERIN (UNII: PDC6A3C0OX)	
ZINC SULFATE (UNII: 89DS0H96TB)	
HAMAMELIS VIRGINIANA FLOWER WATER (UNII: 222MYC9QUV)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
LEMON OIL (UNII: I9GRO824LL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79297-020-01	30 mL in 1 POUCH; Type 0: Not a Combination Product	06/24/2020	
2	NDC:79297-020-05	5 mL in 1 PACKET; Type 0: Not a Combination Product	06/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/24/2020	

Labeler - Au Natural Organics Company (078830844)

Establishment

Name	Address	ID/FEI	Business Operations
Au Natural Organics Company		078830844	manufacture(79297-020)

Revised: 6/2020 Au Natural Organics Company