HAND SANITIZER- alcohol gel
Tu Negocio En Minutos SA de CV

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.

Tahor 1 Litter Hand Sanitizer

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. TRIETHANOLAMINE BENZOATE (0.125% v/v).
d. Carbomer 940 0.5%
e. 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 70%. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

To decrease bacteria on the skin that could cause disease, Recommended for repeated use

Warnings

For external use only: hands Do not drink Flammable. Keep away from heat and flame

Do not use

- in children less than 2 months of age
- on open skin wounds

Keep out of eyes in case of contact with eyes, flush thoroughly with water, Avoid contact with broken skin,

Do not inhale or ingest.

Skin irritation develops.

If swallowed, get medical help or contact a Poison Control Center Right away.

Directions

Wet hands thoroughly with product and allow to dry without wiping. For children under 6, use only under adult supervision. Not recommended for infants.

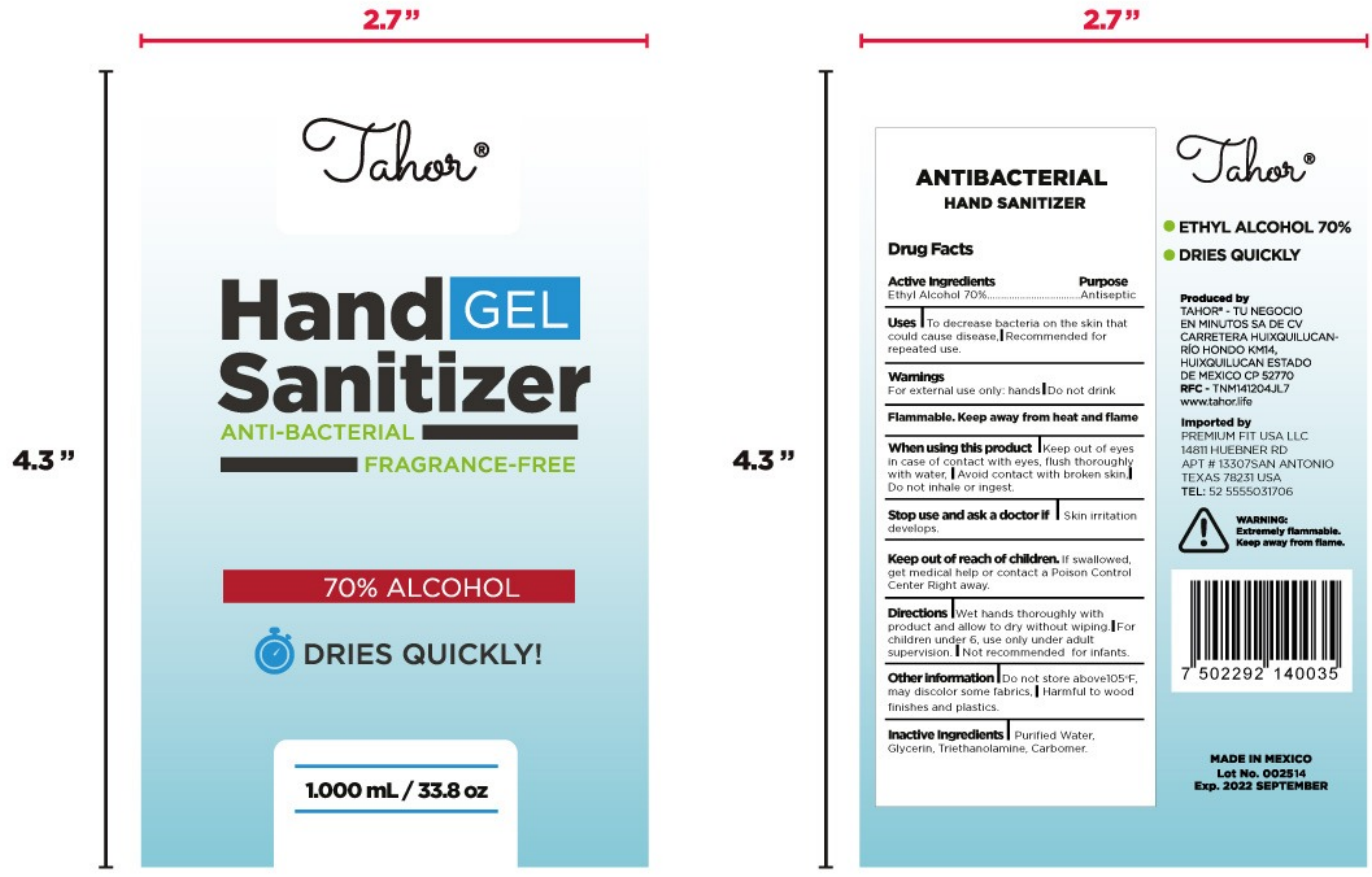
Other information

Do not store above105oF, may discolor some fabrics, Harmful to wood finishes and plastics.

Inactive ingredients

Purified Water, Glycerin, Triethanolamine, Carbomer.

Package Label - Principal Display Panel



1000 mL NDC: 79219-001-02

HAND SANITIZER alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79219-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	0.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79219-001-02	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Tu Negocio En Minutos SA de CV (951578971)

Registrant - Tu Negocio En Minutos SA de CV (951578971)

Revised: 7/2020 Tu Negocio En Minutos SA de CV