HAND SANITIZER- ethyl alcohol gel
H&F TECH INTERNATIONAL, S.A. DE C.V.

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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Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic

Use

Hand Sanitizer to help reduce bacteria on the skin. 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

- Wet hands thoroughly with product and allow to dry without wiping.
- Supervise children under 6 years of age when using this product to avoid swallowing.

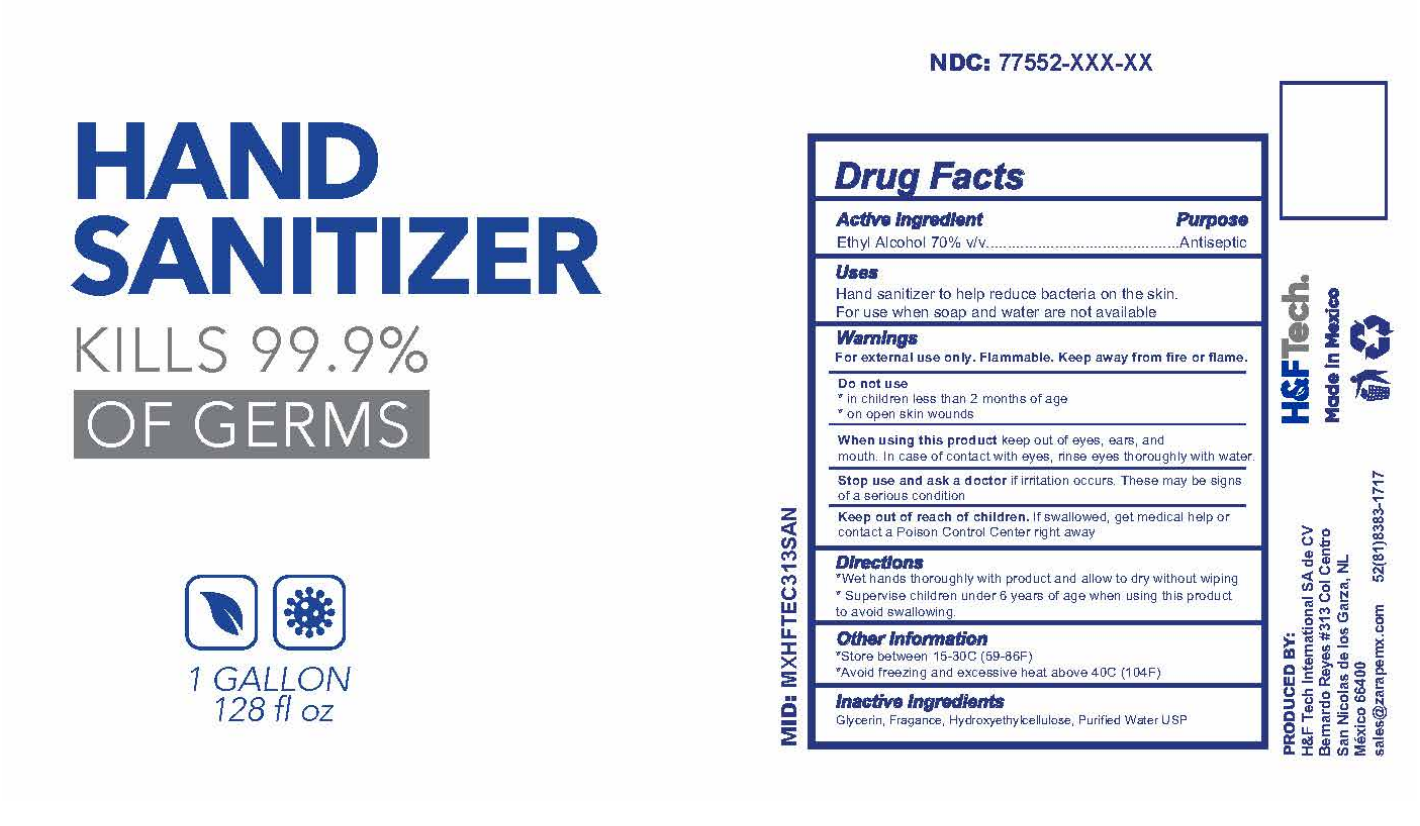
Inactive ingredients

Glycerin, Fragrance, Hydroxyethylcellulose, Purified Water USP

Other information

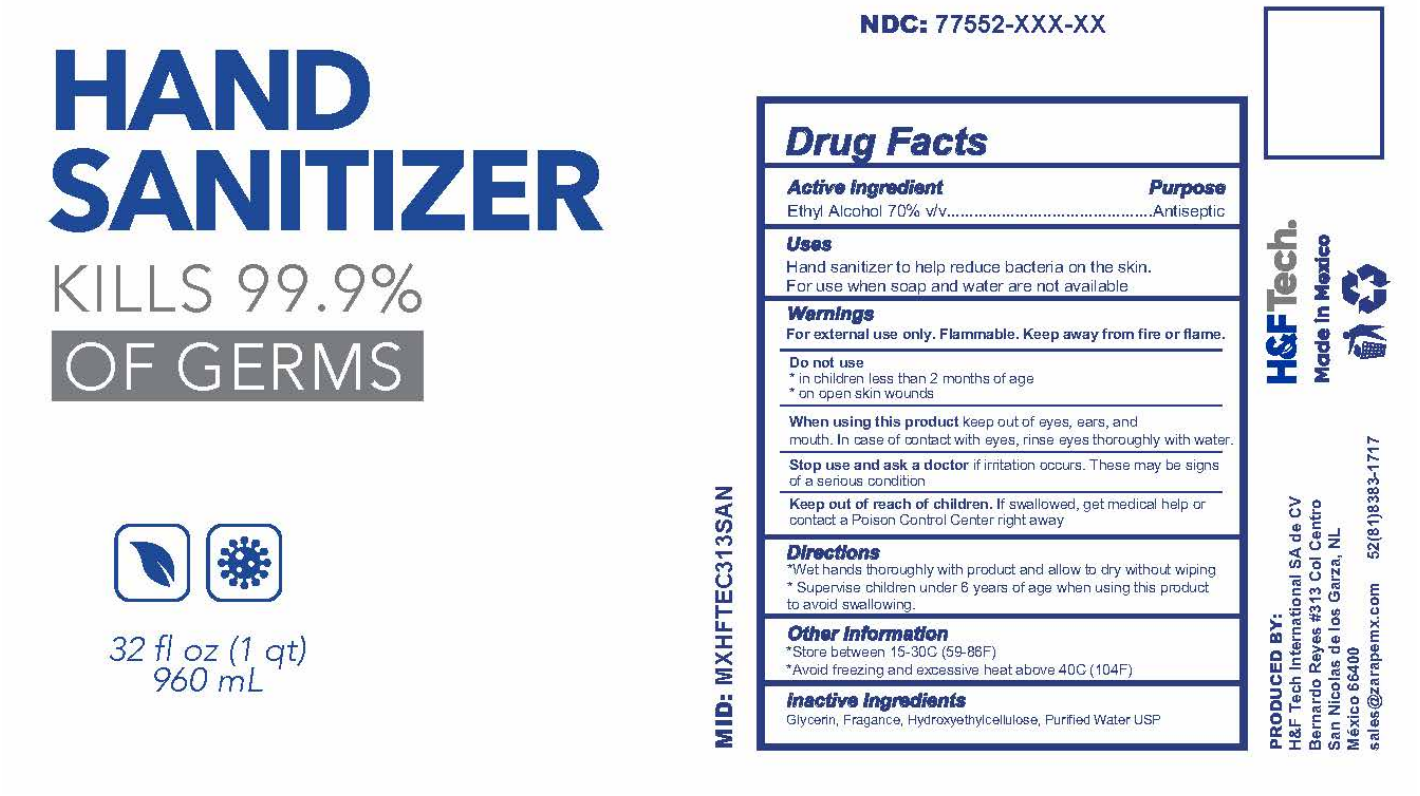
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Package Label - Principal Display Panel



473mL

960mL



HAND SANITIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:77552-005
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**
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:77552-005-	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	

1	01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
2	NDC:77552-005-03	3785.41 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2020	
3	NDC:77552-005-02	960 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/30/2020	

Labeler - H&F TECH INTERNATIONAL, S.A. DE C.V. (814864757)

Establishment

Name	Address	ID/FEI	Business Operations
H&F TECH INTERNATIONAL, S.A. DE C.V.		814864757	manufacture(77552-005)

Revised: 6/2020 H&F TECH INTERNATIONAL, S.A. DE C.V.