

HAND SANITIZER- 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.

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. 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 80% 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.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

125 mL NDC: 77552-001-01

DRUG FACTS	
ACTIVE INGREDIENT ALCOHOL 70% v/v	PURPOSE ANTISEPTIC
USES TO HELP REDUCE BACTERIA THAT POTENTIALLY CAN CAUSE DISEASE. FOR USE WHEN SOAP AND WATER ARE NOT AVAILABLE.	
WARNINGS FOR EXTERNAL USE ONLY: HANDS 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 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 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 GLYCERIN, FRAGRANCE, HYDROXYETHYLCELLULOSE, PURIFIED WATER USP	

MADE IN MEXICO by:
HYF Tech Internacional SA de CV
Bernardo Reyes #313 Col Centro
San Nicolas de los Garza, NL 66400
DISTRIBUTED by:
Sweet Seasons LLC.
10601 S Jackson Rd
Pharr, TX 78577
(956) 687-9910
sales@sweetseasonsllc.com
NDC Code: 76838-001-01

MID: IMAHFEC13SAN LOTE: 001

8 51237 00476 13

500 mL NDC: 77552-001-02

mama CHEDES

Hand Sanitizer

KILLS 99.9% OF GERMS

16.9 FL OZ / 500 ml

DRUG FACTS	
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MID:IMAHFTEC13SSAN LOT#: 001

8 51237 00473 2

900 mL NDC: 77552-001-03

mama CHEDES

Hand Sanitizer

KILLS 99.9% OF GERMS

30.4 FL OZ / 900 ml

DRUG FACTS	
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MID:IMAHFTEC13SSAN LOT#: 001

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3750 mL NDC: 77552-001-04

mama CHEDES
Hand Sanitizer

KILLS 99.9% OF GERMS

1 GALLON / 3750 ml

DRUG FACTS

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NDC Code: 76838-001-04

MID: 1M4HFTEC135AN LOT#: 001

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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77552-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDRO GEN PERO XIDE (UNII: BBX060 AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77552-001-01	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
2	NDC:77552-001-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
3	NDC:77552-001-03	900 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	
4	NDC:77552-001-04	3750 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/27/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/27/2020	

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(77552-001)

Revised: 4/2020

H&F Tech International, S.A. de C.V.