HAND SANITIZER GEL- alcohol gel Wm Refractories, S. de R.L. 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 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:

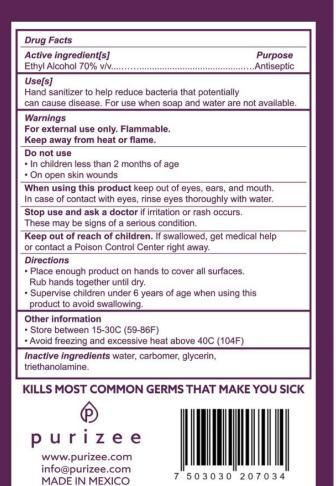
- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water 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.

Active Ingredient(s)



Establishment approved by



20.29 fl.oz.

600 ml

the FDA

Purpose

Antiseptic, Hand Sanitizer

Alcohol 70% v/v. Purpose: Antiseptic

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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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



Establishment approved by the FDA

Drug Facts Active ingredient[s] Ethyl Alcohol 70% v/v.. Use[s] Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available 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. · 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, glycerin, KILLS MOST COMMON GERMS THAT MAKE YOU SICK purizee www.purizee.com info@purizee.com MADE IN MEXICO

600 mL NDC: 75260-340-10

600 ml

HAND SANITIZER GEL

alcohol gel

Product	Information
FIVUUCL	IIIIVI IIIauvii

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:75260-340

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
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

1					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:75260-340-10	600 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - Wm Refractories, S. de R.L. de C.V. (812611254)

Registrant - Wm Refractories, S. de R.L. de C.V. (812611254)

Establishment

Establishinent				
Name	Address	ID/FEI	Business Operations	
Wm Refractories, S. de R.L. de C.V.		8 126 11254	manufacture(75260-340)	

Revised: 5/2020 Wm Refractories, S. de R.L. de C.V.