

HAND SANITIZER- alcohol gel
PORTMOORE TRADING INVESTMENTS LLC

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 ETHYL ALCOHOL 75%

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 75% 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.

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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, denatonin benzoate, carbomer, aloe barbadensis, caprylyl glycol, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Glisser

HANDS AND SKIN

Hand sanitizer

ANTISEPTIC PROTECTION



ETHYL ALCOHOL **75%**

Aloe vera



HYDRATING AND REFRESHING ACTION

KILL 99,99% OF GERMS

BEFORE USING READ THE INSTRUCTIONS

500ml/16,9fl.oz



Introducing the most effective



Glisser antiseptic protection ever

Effective at eliminating more than 99,99% of many common harmful germs & bacteria in as little as 15 seconds

Drug Facts

Active Ingredient

Ethyl alcohol **75%**.....Antiseptic

Purpose

Uses

- to decrease bacteria on the skin that could cause disease
- recommended for repeated use

Warnings

- For external use only: hands
- Flammable, keep away from fire or flame
- Keep out of eyes
- Contact with eyes, wash thoroughly water
- Avoid contact with broken skin
- Do not inhale or ingest

Other information

- do not store above 105°F
- may discolor some fabrics
- harmful to wood finishes and plastics

Stop use ask doctor if

- Irritation and redness develop
- Condition persists for more than 72 hours

Keep out of reach children

- 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

Inactive Ingredients

Ethyl Alcohol.....75%
water, aminomethyl propanol, denatonim benzoate, carbomer, glycerin, aloe barbadenis and caprylyl glycol

date 07/2020

expiration date: 24 months

Glisser

MADE IN BRAZIL

Imported and distributed by
PORTMOORE TRADING INVESTMENTS LLC
3956 W TOWN CENTER BLVD PMB 285
ORLANDO, FL 32837 US
phone (727) 256-5200
www.glisserofficial.com



Flammable
keep away from
fire or flame



Danger keep
out of reach
of children

500 mL NDC: 79736-000-00

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79736-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79736-000-00	48000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/10/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/10/2020	

Labeler - PORTMOORE TRADING INVESTMENTS LLC (117512458)

Registrant - NORONHA PRODUTOS QUIMICOS LTDA (899367239)

Establishment

Name	Address	ID/FEI	Business Operations
NORONHA PRODUTOS QUIMICOS LTDA		899367239	manufacture(79736-000)

Revised: 10/2020

PORTMOORE TRADING INVESTMENTS LLC