

PRO GUARD- alcohol liquid
Edward Roberts, 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.

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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Hydrogen Peroxide 0.125%

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, Aloe Barbadosis leaf juice, fragrance, purified water USP

Package Label - Principal Display Panel

PRO GUARD
Alcohol Wipes

TO OPEN PACKAGE:

1. Open lid and pull out wipe from center of roll.

2. The next sheet pops up automatically.

3. When finished, discard to retain moisture.

GOOD FOR AFTER USE

WC, PHONE DEVICE, ON-THE-GO, KITCHEN, GYM, SHOPPING, OFFICE, RESTAURANT, TRAVEL

Keep it clean, whether you're at work or home, the grocery store, in your car, gym, on a plane or at the playground.

Pro Guard Sanitizing Alcohol Wipes is made with 75% alcohol, aloe vera and other fine ingredients that effectively clean while keeping your hands hydrated. Perfect when you're on-the-go, especially when soap and water are not available.

Gentle on hands, made without parabens, sulfate, chlorine or bleach.

CARING CAUTION: For external use only. Not for use as a baby wipe. Do not use in genital area or on damaged skin. Do not get in eyes. Discontinue use if irritation or redness occurs and persists. Flammable. Keep away from fire or flame, heat, spark, and electrical.

STORAGE AND DISPOSAL: Dispose of wipe in trash after use. Do not flush. Tightly close lid between uses to retain moisture.

Nonrecyclable container. Do not reuse or refill this empty container. Discard empty container in trash or recycle (if available).

Drug Facts

Active ingredient	Purpose
Isopropyl Alcohol 75%	Antibacterial
Hydrogen Peroxide 0.125%	Antimicrobial

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 cuts or sores

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.

Directions

- To dispense, lift cover, remove seal, pull center sheet from roll, hold to a point and feed through dispenser hole in cover. Keep lid closed to prevent moisture loss.
- Open and unfold wipe.
- Thoroughly wipe hands, fingers and wrists. Be sure to use the entire wipe. Allow to dry.
- For dirty hands, use first wipe to clean hands, then discard wipe; sanitize with the second wipe.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

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

Inactive ingredients Water (aqua), aloe vera, aloe barbadensis (aloe vera) leaf juice, fragrance (parfums).

80 Wipes

Net Wt. 1.74 lbs (789 g)
7 in x 7.25 in
17.78 cm x 18.415 cm

PRO GUARD
ALCOHOL WIPES

75% ALCOHOL KILLS 99.9% OF GERMS & BACTERIA*

Good for after use

- + Targets Bacteria
- + Antimicrobial Formula
- + Kills Germs
- + Tough Sanitizing Formula

FRESH LEMON

KEEP OUT OF REACH OF CHILDREN
SEE BACK PANEL FOR ADDITIONAL CAUTION: PRECAUTIONARY STATEMENTS

ACTIVE INGREDIENTS:

Isopropyl Alcohol	75.000%
Hydrogen Peroxide	0.125%
Other Ingredients	24.875%

MADE IN USA with organic components

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000 ml NDC: 00000-000-00

PRO GUARD

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80370-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	0.125 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	24.875 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80370-001-80	80 mL in 1 CANISTER; Type 0: Not a Combination Product	08/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/17/2020	

Labeler - Edward Roberts, LLC (116422326)

Revised: 8/2021

Edward Roberts, LLC