

HAND SANITIZER- isopropyl alcohol solution
Guardian Chemicals Inc.

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.

IPA 1L, 2x1L Traxol,

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

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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

1000 ml NDC: 76787-002-07

**ISOPOROPYL ALCOHOL
ANTISEPTIC
75% TOPICAL SOLUTION**

HAND SANITIZER NON-STERILE SOLUTION

1000 mL

TRAXOL
CHEMICALS

TRAXOL CHEMICALS - A DIVISION OF GUARDIAN CHEMICALS INC
155-55202 SH 825 STURGEON INDUSTRIAL PARK, STURGEON COUNTY, ALBERTA, CANADA, T8L 5C1
PHONE: TOLL FREE (800) 881-6544

Drug Facts
Active Ingredient(s) Purpose:
Isopropyl Alcohol 75%v/v Antiseptic


Use[s]
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DANGER - FLAMMABLE

READ THE SAFETY DATA SHEET FOR FURTHER INFORMATION.
FOR EMERGENCY SPILL INFORMATION OR TO REORDER:
CALL TOLL FREE 1-800-661-6544. READ THE LABEL BEFORE USING.
LIMITED QUANTITY

LOT NUMBER:
NET CONTENTS: 1 LITRE
NDC: 76787-002-07


8 37068 00004 4

2x1000 mL bag label NDC: 76787-002-08



**GUARDIAN
CHEMICALS
INC.**

**ISOPROPYL ALCOHOL ANTISEPTIC
75% TOPICAL SOLUTION
Hand Sanitizer Non-Sterile Solution**



8 37068 00023 5

**2 x 1L Liquid Hand Sanitizer
SOLD AS A SET**

NDC 76787-002-08

HAND SANITIZER

isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76787-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL 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:76787-002-07	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/17/2020	
2	NDC:76787-002-08	2 in 1 BAG	07/17/2020	
2	NDC:76787-002-07	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/17/2020	

Labeler - Guardian Chemicals Inc. (254092356)**Establishment**

Name	Address	ID/FEI	Business Operations
Guardian Chemicals Inc.		254092356	manufacture(76787-002)

Revised: 7/2020

Guardian Chemicals Inc.