HAND SANITIZER- is opropyl 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

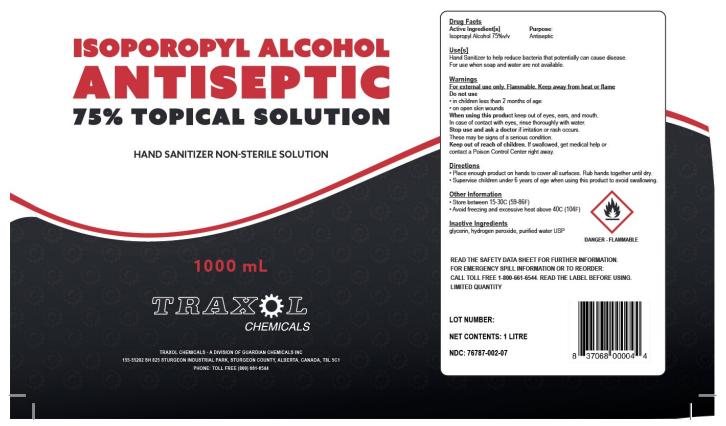
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

1000 ml NDC: 76787-002-07



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



ISOPROPYL ALCOHOL ANTISEPTIC 75% TOPICAL SOLUTION

Hand Sanitizer Non-Sterile Solution



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

NDC 76787-002-08

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

	Packaging			
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:76787-002- 07	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/17/2020	
:	NDC:76787-002- 08	2 in 1 BAG	07/17/2020	
:	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.