

HAND SANITIZER- isopropyl alcohol gel **Seitz "the Fresher Company", 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.

Hand Sanitizer

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



The fresher company.

BAVICID ISO GEL

Isopropyl Alcohol 75% (V/V)



**HAND
DISINFECTANT**

Bavacid Iso Gel is a ready-for-use alcohol-based solution for hygienic and medical hand disinfection.



The fresher company.

Bavacid Iso Gel is a ready to use hand disinfection product with active ingredients of Isopropyl Alcohol 75% (V/V) Highly effective to kill germs and virus instantly. Please report any adverse effect not listed here to your physician or pharmacist

Bavacid Iso Gel is normally used for general hygiene and medical

How to use Pour product on hands and rub until dry **Caution** not to be consumed, do not use near eyes and open wounds. Highly flammable, keep away from source of ignition, heat and fire. Keep out of reach of children. Store below 35°C

Active Ingredient Isopropyl Alcohol 75% (V/V), **Other Ingredients:** Purified water, and Polymer.

Distributed by:

SEITZ, The Fresher Company, Inc
5101 Tampa West Blvd
Tampa, FL 33634 - USA

Innovations
since **1885**

Be a constant developer just for your customers

UN 1219



200kg

Batch No:

Exp Date:

200 ml NDC: 76545-0155

HAND SANITIZER

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76545-0155
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL
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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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76545-0155-1	200000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76545-0155-2	355 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - Seitz "the Fresher Company", Inc (124767000)

Establishment

Name	Address	ID/FEI	Business Operations
Seitz "the Fresher Company", Inc		124767000	relabel(76545-0155) , manufacture(76545-0155)

Revised: 5/2020

Seitz "the Fresher Company", Inc