INSTA SAN- isopropyl alcohol liquid Freedom Technologies

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

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



15520 Illinois Ave. Paramount, CA 90723 Ph: 562.633.6150 Fax: 562.633.6158

INSTA SAN

Drug Facts Active ingredient[s] Purpose Isopropyl alcohol 75% 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 · 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 • 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 Manufactured by Freedom Technologies, LLC Paramount, CA 90723 Made in the USA





HEALTH (SALUD)

FLAMMABILITY



REACTIVITY (REACTIVATED)

(INFLAMMABLE IDAD)



PERSONAL PROTECTION



THESE HMIS RATINGS ARE SUPPLIED AT BUYERS REQUEST. SELLER ASSUMES NO OBLIGATION OR LIABILITY FOR THE ADVICE OR ASSISTANCE GIVEN OR RESULTS OBTAINED.

5 GALLONS

FT082020

Net Weight:

000 ml NDC: 00000-000-00

INSTA SAN

.ot #:

isopropyl alcohol liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80891-101

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		
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL		

WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80891- 101-01	3785 mL in 1 JUG; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80891- 101-02	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2020	

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

Labeler - Freedom Technologies (057382260)

Establishment				
Na me	Address	ID/FEI	Business Operations	
Freedom Technologies		057382260	manufacture(80891-101)	

Revised: 1/2022 Freedom Technologies