SANI-GEL HAND SANITIZER- isopropyl alcohol gel 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.

Sani-Gel 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

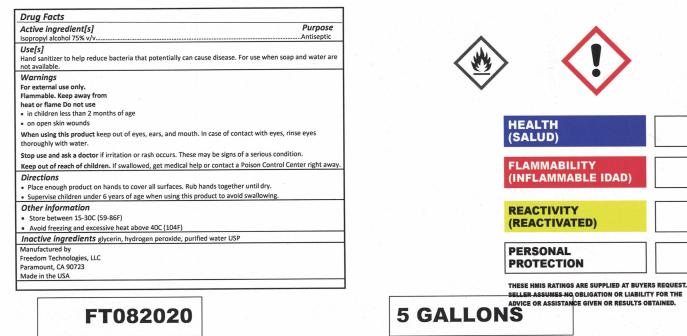
glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



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

SANI-GEL HAND SANITIZER



Lot #:_

Net Weight:

000 ml NDC: 00000-000-00

SANI-GEL HAND SANITIZER							
isopropyl alcohol gel							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:80891-123			
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingredient Name			Basis of Strengt	Strengt			
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)

WATER (UNII: 059QF0K00R)

Packaging								
#	Item Code	Package	e Description	Marketing Start Date	Marketing End Date			
-	NDC:80891-123- 01	DC:80891-123- I Product 3785 mL in 1 JUG; Type 0: Not a Combination		03/30/2020				
Μ	arketing	Information						
M	arketing Marketing Category		lumber or Monograph Citation	Marketing Start Date	Marketing End Date			

Labeler - Freedom Technologies (057382260)

Establishment

Name	Address	ID/FEI	Business Operations
Freedom Technologies		057382260	manufacture(80891-123)

Revised: 1/2022

Freedom Technologies