PSSI I-SAN- isopropyl alcohol liquid
PSSI Chemical Innovations

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

3.78 L NDC: 69886-112-02

PSSI™
CHEMICAL INNOVATIONS

PSSI I-SAN

Isopropyl Alcohol Antiseptic 75%
Topical Solution

Hand Sanitizer
Non-sterile Solution

DANGER. Highly flammable liquid and vapor. Causes serious eye irritation. May cause respiratory irritation. May cause drowsiness or dizziness.
Prevention: Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Use explosion-proof electrical/ventilating/lighting/equipment. Wear eye/face protection. Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area. **Response: IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. **IF INHALED:** Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell. **IN CASE OF FIRE:** Use CO2, dry chemical, or foam for extinction. **Storage:** Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up. **Disposal:** Dispose of contents/container to an approved waste disposal plant.

READ SDS BEFORE USING THIS PRODUCT.

BATCH: _____

FOR INDUSTRIAL USE ONLY
NOT FOR RETAIL SALE   ID #20045

NET CONTENTS: 50 U.S. GALLONS (189.27 LITERS)

Drug Facts

Active ingredient[s]	Purpose
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CERTIFIED BY SQF QUALITY SUPPLIER AIBI-CS 34046

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Kieler, WI 53812 USA
888-671-5366

CHEMTREC   EMERGENCY   PHONE   1-800-424-9300

UN1993, Flammable liquids, n.o.s., 3, PG II, (contains isopropanol)

PSSI I-SAN
isopropyl alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69886-112
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:69886-112-02	3780 mL in 1 BOTTLE; 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 - PSSI Chemical Innovations (114206972)

Establishment

Name	Address	ID/FEI	Business Operations
Packers Chemical, Inc.		114206972	manufacture(69886-112)

Revised: 4/2020

PSSI Chemical Innovations