

PSSI E-SAN- alcohol liquid

Safe Foods 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.

PSSI E-San 4x1G, 1G

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. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (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)

Alcohol 80% 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



PSSI E-SAN

Alcohol Antiseptic 80%
Topical Solution
Hand Sanitizer
Non-sterile Solution



DANGER. Highly flammable liquid and vapor. Causes serious eye irritation.
READ SDS BEFORE USING THIS PRODUCT.

NET CONTENTS: 1 GALLON (3.78 LITERS)

Drug Facts	
Active ingredient[s]	Purpose
Alcohol 80% v/v.....	Antiseptic
Use[s]	
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.	
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NDC# 69886-111-02

Safe Foods Chemical Innovations

FOR INDUSTRIAL USE ONLY
NOT FOR RETAIL SALE
ID #20044

1501 8th Street
North Little Rock, AR 72114 USA
701-758-8500



PSSI E-SAN

Alcohol Antiseptic 80%
Topical Solution
Hand Sanitizer
Non-sterile Solution

DANGER. Highly flammable liquid and vapor. Causes serious eye irritation.

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. **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. **IN CASE OF FIRE:** Use CO2, dry chemical, or foam for extinction. **Storage:** Store locked up. Store in a well-ventilated place. Keep cool. **Disposal:** Dispose of contents/container to an approved waste disposal plant.

READ SDS BEFORE USING THIS PRODUCT.

NET CONTENTS: 4x1 U.S. GALLONS (15.14 LITERS)

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NOT FOR RETAIL SALE
ID #20044

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Active ingredient[s]	Purpose
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CHEMTREC EMERGENCY PHONE 1-800-424-9300

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

PSSI E-SAN

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69886-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.08 L in 0.1 L

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	0.00145 L in 0.1 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.000125 L in 0.1 L
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69886-111-02	3.78 L in 1 JUG; Type 0: Not a Combination Product	09/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/01/2020	

Labeler - Safe Foods Chemical Innovations (114206972)

Registrant - Safe Foods Chemical Innovations (114206972)

Establishment

Name	Address	ID/FEI	Business Operations
Higley Industries Inc.		005467626	manufacture(69886-111)

Revised: 3/2023

Safe Foods Chemical Innovations