

## **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.*

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### **PSSI E-San 50G dr.**

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.

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.

### **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.**  
**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 CO<sub>2</sub>, 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.

BATCH:  EXP:

FOR INDUSTRIAL USE ONLY  
NOT FOR RETAIL SALE  
ID #20044

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

| <b>Drug Facts</b>  |                |
|--|----------------|
| <i>Active ingredient[s]</i>  | <i>Purpose</i> |
| Alcohol 80% v/v.....   | Antiseptic     |
| <i>Use[s]</i>  |                |
| Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  |                |
| <i>Warnings</i>  |                |
| <b>For external use only. Flammable. Keep away from heat or flame</b>  |                |
| <i>Do not use</i>  |                |
| <ul style="list-style-type: none"> <li>• in children less than 2 months of age</li> <li>• on open skin wounds</li> </ul>   |                |
| <i>When using this product</i>   |                |
| keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.   |                |
| <i>Stop use and ask a doctor</i>   |                |
| if irritation or rash occurs. These may be signs of a serious condition.   |                |
| <i>Keep out of reach of children.</i>  |                |
| If swallowed, get medical help or contact a Poison Control Center right away.  |                |
| <i>Directions</i>  |                |
| <ul style="list-style-type: none"> <li>• Place enough product on hands to cover all surfaces. Rub hands together until dry.</li> <li>• Supervise children under 6 years of age when using this product to avoid swallowing.</li> </ul> |                |
| <i>Other information</i>   |                |
| <ul style="list-style-type: none"> <li>• Store between 15-30C (59-86F)</li> <li>• Avoid freezing and excessive heat above 40C (104F)</li> </ul>  |                |
| <i>Inactive ingredients</i>  |                |
| glycerin, hydrogen peroxide, purified water USP  |                |



CHEMTREC EMERGENCY PHONE 1-800-424-9300

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

**NDC# 69886-111-02**

**Safe Foods Chemical Innovations**  
1501 8th Street  
North Little Rock, AR 72114 USA  
701-758-8500

## PSSI E-SAN

alcohol liquid

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69886-111 |
| <b>Route of Administration</b> | 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:69886-111-03 | 189.27 L in 1 DRUM; 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 |         | 005467626 | manufacture(69886-111) |

Revised: 3/2023

Safe Foods Chemical Innovations