PHLEXSAN GEL ALCOHOL HAND SANITIZER- alcohol gel
GLOBAL CO PAK LLC

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. 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 70% 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)

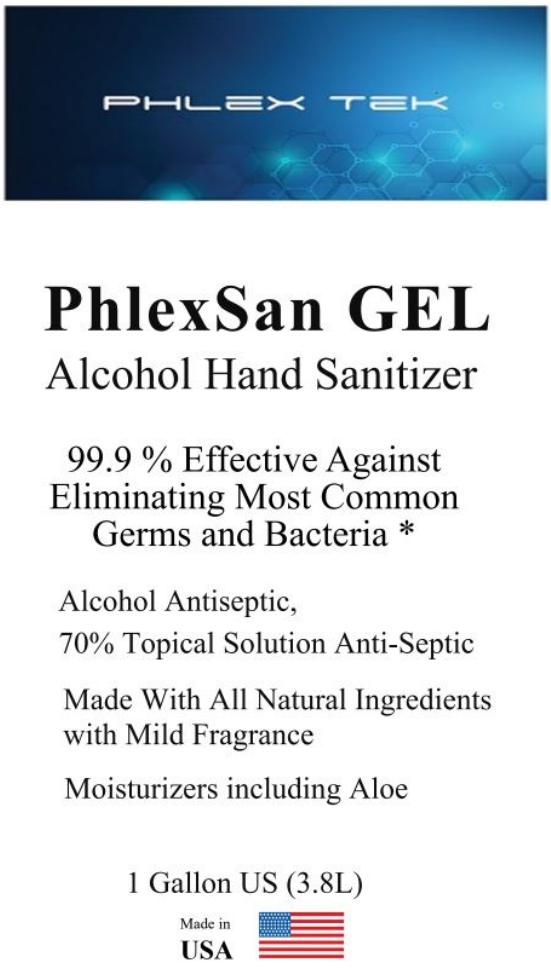
Inactive ingredients

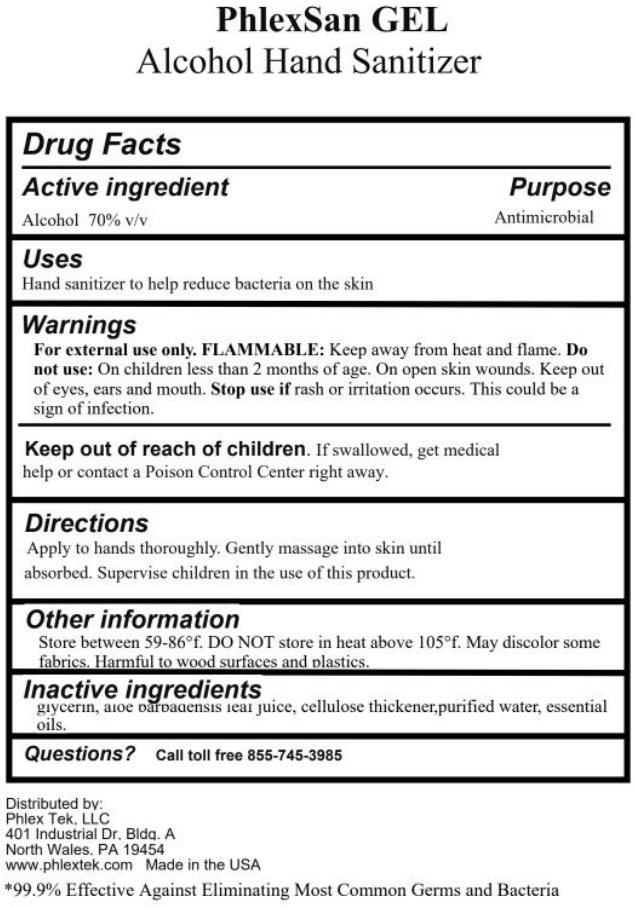
glycerin, aloe, cellulose, thickener, essential oils, purified water USP

Package Label - Principal Display Panel
PhlexSan 1 Gallon
PhlexSan 16oz

3785 mL NDC: 80892-004-01

PhlexSan Gel 128oz.jpg





473 mL NDC: 80892-004-16

PhlexSan Gel 16oz.jpg

PhlexSan GEL

Alcohol Hand Sanitizer

99.9 % Effective Against Eliminating Most Common Germs and Bacteria *

Alcohol Antiseptic,
70% Topical Solution Anti-Septic

Made With All Natural Ingredients with Mild Fragrance

Moisturizers including Aloe

16 FL OZ (473mL)

Made in USA

PhlexSan GEL
Alcohol Hand Sanitizer

Drug Facts

Active ingredient — **Purpose**

Alcohol 70% v/v — Antimicrobial

Uses

Hand sanitizer to help reduce bacteria on the skin

Warnings

For external use only. FLAMMABLE: Keep away from heat and flame. **Do not use:** On children less than 2 months of age. On open skin wounds. Keep out of eyes, ears and mouth. **Stop use if** rash or irritation occurs. This could be a sign of infection.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply to hands thoroughly. Gently massage into skin until absorbed. Supervise children in the use of this product.

Other information

Store between 59-86°f. DO NOT store in heat above 105°f. May discolor some fabrics. Harmful to wood surfaces and plastics.

Inactive ingredients

glycerin, aloe barbadensis leaf juice, cellulose thickener,purified water, essential oils.

Questions? Call toll free 855-745-3985

Distributed by:
Phlex Tek, LLC
401 Industrial Dr, Bldg. A
North Wales, PA 19454
www.phlextek.com Made in the USA

*99.9% Effective Against Eliminating Most Common Germs and Bacteria

PHLEXSAN GEL ALCOHOL HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80892-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE (UNII: V5VD430YW9)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80892-004-01	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:80892-004-64	1892 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
3	NDC:80892-004-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:80892-004-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
5	NDC:80892-004-08	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
6	NDC:80892-004-04	119 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
7	NDC:80892-004-02	60 mL in 1 BOTTLE, PUMP; 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 - GLOBAL CO PAK LLC (117638624)

Establishment

Name	Address	ID/FEI	Business Operations
Four Fathers Distillery LLC		085564625	manufacture(80892-004)

Establishment

Name	Address	ID/FEI	Business Operations
GLOBAL CO PAK LLC		117638624	relabel(80892-004)

Revised: 12/2020 GLOBAL CO PAK LLC