HAND SANITIZER 80%- alcohol liquid Phibro Animal Health Corporation

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.

Hand Sanitizer, Alcohol 80%

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.

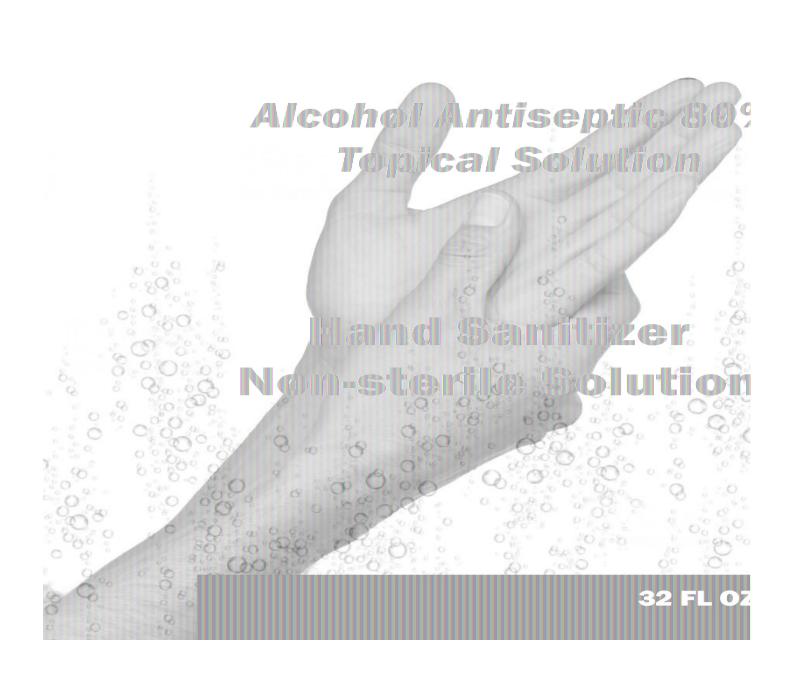
Other information

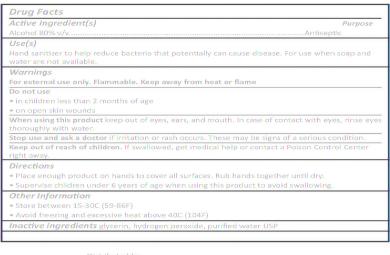
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel







Distributed by: Osprey Biotechnics *a Division of Phibro Animal Health Corporation* 1845 57th Street Sarasota, FL 34243



944 mL NDC: 66104-0080-1

HAND SANITIZER 80%

alcohol liquid							
Product Inform	ation						
Product T ype		HUMAN OTC DRUG Item Code (Source			e) NDC:66104-0080		
Route of Administr	ration	TOPICAL					
A T . 11							
Active Ingredient/Active Moiety Ingredient Name Bas						n Strength	
				ALCOH	of Strength	80 mL in 100 mL	
Inactive Ingredients							
Ingredient Name					Strength 1.45 mL in 100 mL		
GLYCERIN (UNII: PDC6A3C0OX) HYDROGEN PEROXIDE (UNII: BBX060AN9V)					0.125 mL in 100 mL		
WATER (UNII: 059QF0K00R)							
Packaging							
# Item Code		Package Description			keting Start Date	Marketing End Date	
1 NDC:66104- 0080-1	944 mL in 1 BO Product	in 1 BOTTLE, PLASTIC; Type 0: Not a Combination		04/29/2020			
Marketing In	formation						
Marketing Category Applica		tion Number or Monograph Citation		Marketing Start Date		Marketing End Date	
OTC monograph not final part333.			C				

Labeler - Phibro Animal Health Corporation (006989008)

Registrant - Phibro Animal Health Corporation (080154345)

Establishment

Name	Address	ID/FEI	Business Operations
Phibro Animal Health Corporation		080154345	api manufacture(66104-0080)

Revised: 4/2020

Phibro Animal Health Corporation