HAND SANITIZER- alcohol liquid Byrnes and Kiefer Company

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

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.

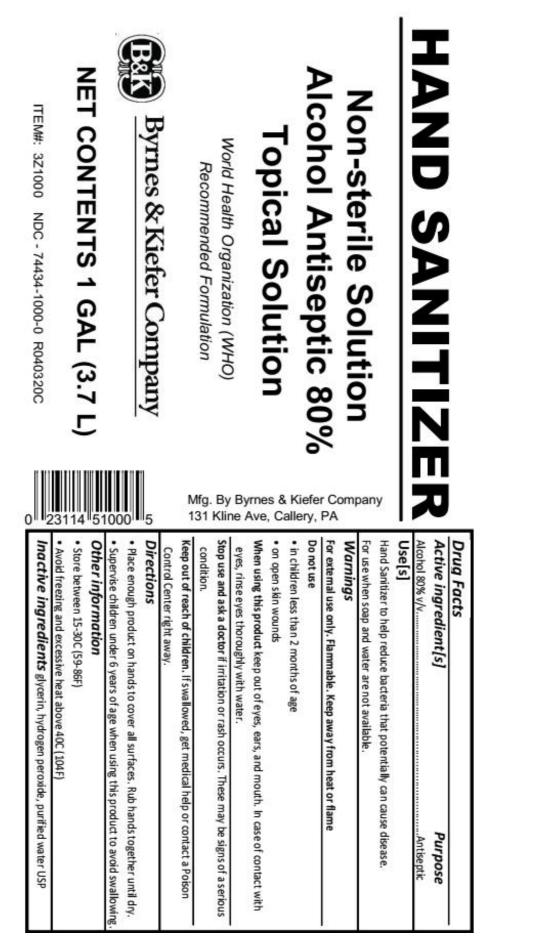
Other information

- 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



3700 mL NDC: 74434-1000-0

HAND SANITIZER alcohol liquid									
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Product Information									
Product Type		HUMAN OTC DRUG	Item Code (Source)		NDC:74434-1000				
Route of Administra	tion	TOPICAL							
Active Ingredient/Active Moiety									
Ingredient Name					of Strengtl	n Strength			
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V9				ALCOHO)L	80 mL in 100 mL			
Inactive Ingredients									
	Ing		Strength						
GLYCERIN (UNII: PDC6A3C0OX)					1.45 mL in 100 mL				
HYDRO GEN PERO XI	0 AN9 V)		0.125 mL in 100 mL						
WATER (UNII: 059QF0KO0R)									
Packaging									
# Item Code		Package Description		Marketing	Start Date	Marketing End Date			
1 NDC:74434-1000-0	3700 mL in 1 JU	JG; Type 0: Not a Combination Product 04		04/03/2020					
Marketing Information									
Marketing Catego	ry Applicat	ion Number or Monograph C	itation	Marketin	g Start Date	Marketing End Date			
OTC monograph not fin	nal part333A			0 4/0 1/20 20					

Labeler - Byrnes and Kiefer Company (004370714)

Establishment									
Name	Address	ID/FEI	Business Operations						
Byrnes and Kiefer Company		004370714	manufacture(74434-1000)						

Revised: 4/2020

Byrnes and Kiefer Company