

HAND SANITIZER- alcohol liquid

Blue Cat

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 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

3.875L NDC:78415-001-01

1 GAL BC WHO sanitizer.jpg

<p>WATERLESS HAND SANITIZER is an 80% v/v Ethyl Alcohol Antiseptic Solution.</p> <p>HAZARD STATEMENTS May cause eye irritation. May be harmful if swallowed.</p> <p>PRECAUTIONARY STATEMENTS Forms smooth, slippery surfaces on floors, posing an accident risk.</p> <p>STORAGE AND HANDLING Store in a dry and well-ventilated place. Store in a closed container. Keep cool. Use / follow appropriate industrial practice.</p> <p>SPILL RESPONSE Wipe away or for larger spills, dike area in front / around spill and contain for appropriate disposal.</p> <p>SHIPPING DESCRIPTION ORM-D, Consumer Commodity, in accordance with 49CFR (HMR 181), 173.150 and 173.156. Ethyl alcohol solutions, 3, UN1170, PG II</p>	 <p>Luxury Amenities</p> <p>ALCOHOL ANTISEPTIC 80% TOPICAL SOLUTION</p> <p>Hand Sanitizer</p> <p>NON-STERILE SOLUTION</p> <ul style="list-style-type: none"> ✓ PARABEN FREE ✓ GLUTEN FREE ✓ SULFATE FREE ✓ MADE IN THE USA <p>waterless hand sanitizer</p> <p>3785 mL (1 US GALLON - 128 US FL OZ)</p>	<p>DRUG FACTS</p> <table border="1"> <thead> <tr> <th>ACTIVE INGREDIENT</th> <th>PURPOSE</th> </tr> </thead> <tbody> <tr> <td>Alcohol 80% v/v.....</td> <td>Antiseptic</td> </tr> </tbody> </table> <p>USE(S) Hand sanitizer to help reduce bacteria that can potentially cause disease. For use when soap and water are not available.</p> <p>WARNINGS Flammable. Keep away from fire or flame. For external use only. Do not use in children less than 2 months of age or on open skin wounds. When using this product, keep out of eyes, ears and mouth. In case of contact, 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 Poison Control Center right away.</p> <p>DIRECTIONS •Place enough product on hands to cover all surfaces then rub hands together until dry. •Supervise children under 6 years of age when using this product to avoid swallowing.</p> <p>INACTIVE INGREDIENTS Glycerin, hydrogen peroxide, purified water USP</p> <p>OTHER INFORMATION •Store between 15-30C (59-86F) and avoid freezing and excessive heat above 40C (104F).</p> <p>BLUE CAT PRODUCTS ©2020 BLUE CAT PRODUCTS. ALL RIGHTS RESERVED</p>	ACTIVE INGREDIENT	PURPOSE	Alcohol 80% v/v.....	Antiseptic
ACTIVE INGREDIENT	PURPOSE					
Alcohol 80% v/v.....	Antiseptic					
<p>Consult SDS for Full Statements of Health, Safety, & Environmental Information</p> <p>Transportation / Spill 24 - Hour Emergency Phone Number: 1-800-424-9300 / +1 703-527-3887</p>						

HAND SANITIZER

alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78415-001

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 L in 100 L	
Inactive Ingredients				
	Ingredient Name	Strength		
	GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L		
	HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L		
	WATER (UNII: 059QF0K00R)	18.425 L in 100 L		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78415-001-01	3.875 L in 1 BOTTLE; 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 - Blue Cat (795910491)

Registrant - Custom Blenders (057505117)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Blenders		057505117	manufacture(78415-001)