

HAND SANITIZER- ethanol gel

Biological Health Group

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)

Ethanol 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.

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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.

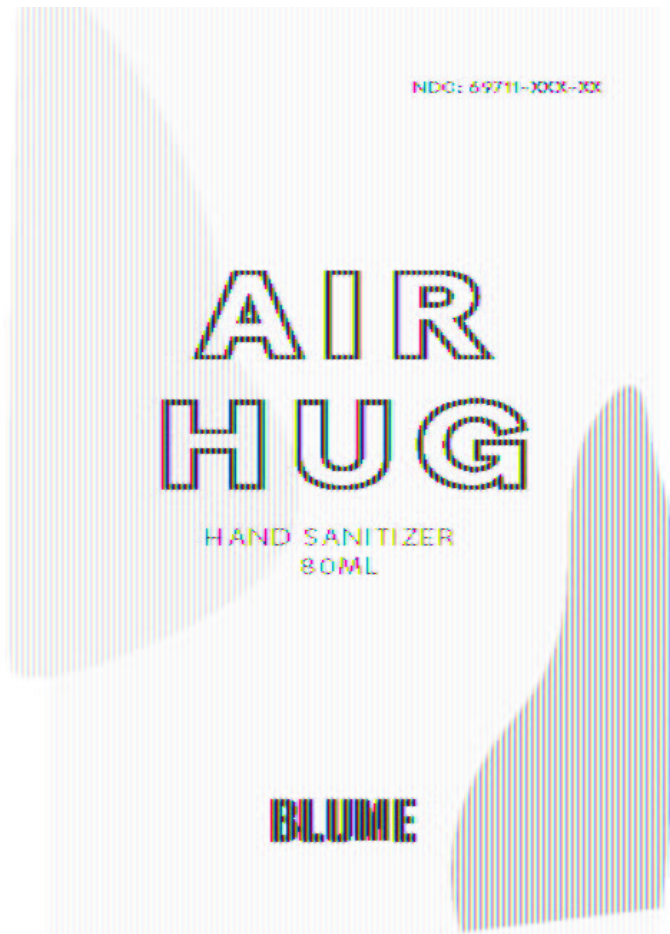
Other information

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

Inactive ingredients

Aqua, Aloe vera leaf juice, glycerin, isopropyl myristate, propylene glycol, tocopherol, aminomethyl propanol, carbomer

Package Label - Principal Display Panel



Drug Facts
Active Ingredient Ethanol (70%).....
Use(s) Hand Sanitizer to help potentially can cause and water are not av
Warnings For external use only. Flammable. Keep away
Do not use • In children less than • on open skin or wat
When using this prod and mouth. In case of eyes thoroughly with
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Keep out of reach of medical help or cont right away.
Directions • Place enough prod surfaces. Rub hand • Supervise children using this product 1
Other Information • Store between 15-3 • Avoid freezing & ex (104F)
Inactive Ingredient Aqua, Aloe Barbaden Glycerin, Isopropyl M Tocopheryl Acetate (A Propanol, Carbomer
Manufactured for Blume, 44 Made in Canada 1-888-27

HAND SANITIZER

ethanol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69711-802
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
CARBOMER 940 (UNII: 4Q93RCW27E)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
AMINOMETHYL PROPANEDIOL (UNII: CZ7BU4QZJZ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69711-802-01	80 mL in 1 TUBE; 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 - Biological Health Group (079767886)**Establishment**

Name	Address	ID/FEI	Business Operations
Deserving Health International Corp.		202617023	manufacture(69711-802)

Revised: 4/2020

Biological Health Group