**PFA- alcohol gel**
**BLUE SEA AEROSOL & DAILY CARE CO., LTD**

*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.*

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**NYC Health+ Hospitals 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)

Ethyl Alcohol 70%(v/v)

## Purpose

Purpose: Antimicrobial

## Use

Hand sanitizing to help reduce bacteria on the skin.

## Warnings

For external use only. Flammable. Keep away from fire or flame

When using this product avoid contact with the eyes. In case of contact, flush eyes thoroughly with water.

Stop use and ask a doctor if irritation and redness develops or persists.

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

**Directions**

- Put enough product in the palm to cover hands & rub together briskly until the liquid is dry
- Children under 6 should be supervised when using Sanitizers.

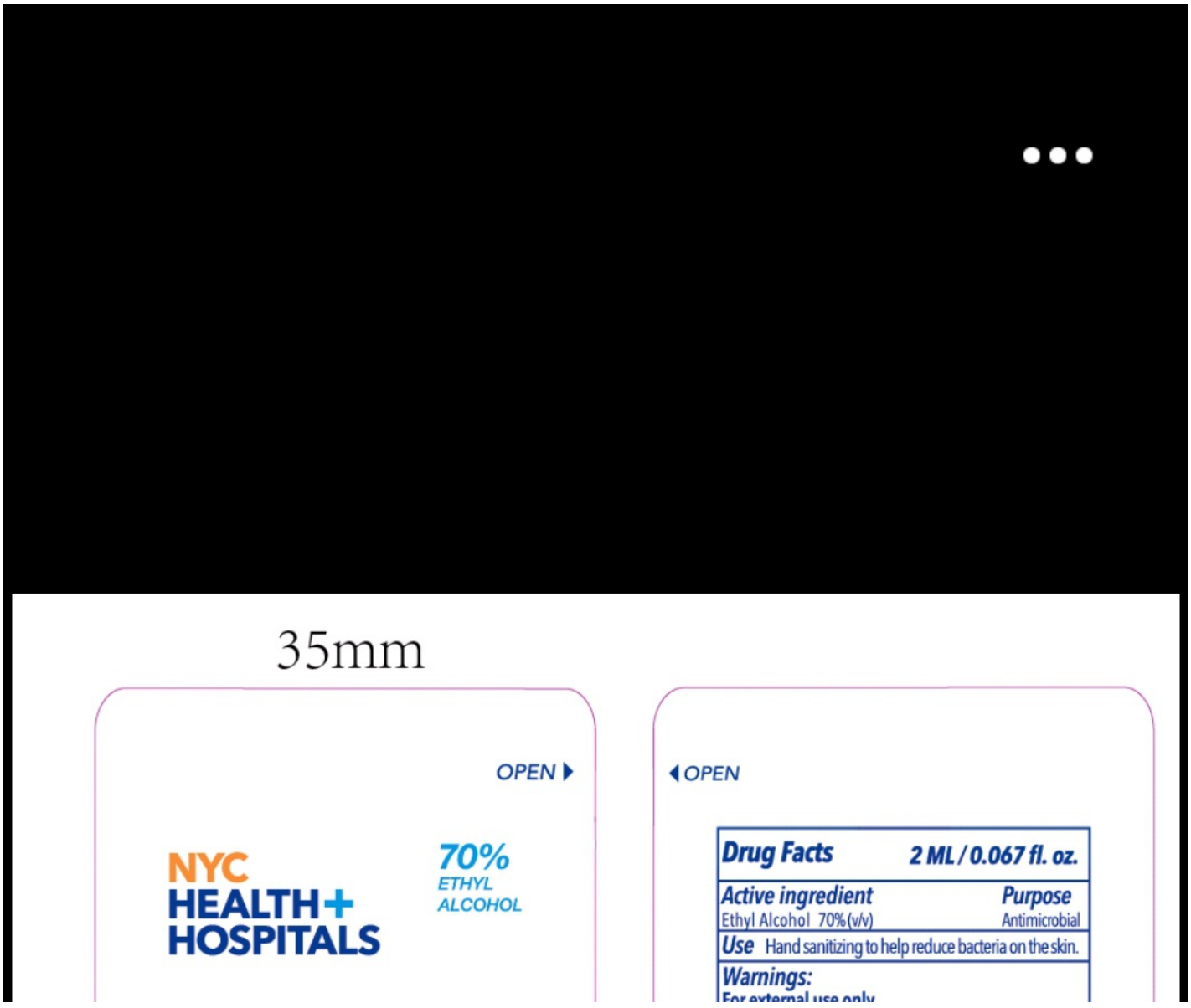
**Other information**

- Store below 110F (43C)
- May discolor certain fabrics or surfaces.

**Inactive ingredients**

Carbomer, Glycerin, Grapefruit seed extract, Mentha Oil, Propylene glycol, Purified water, Sophora extract, Triethanolamine

**Package Label - Principal Display Panel**



80mm

# HAND SANITIZER

**KILLS 99.99%* OF GERMS**

*During in vitro studies

- MINT OIL
- SOPHORA EXTRACT
- GRAPEFRUIT EXTRACT

**2ml**

For external use only.

**Flammable.** Keep away from fire or flame.

**When using this product** avoid contact with the eyes. In case of contact, flush eyes thoroughly with water.

**Stop use and ask a doctor** if irritation and redness develops and persists.

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

***Directions*** • Put enough product in the palm to cover hands & rub together briskly until the liquid is dry • Children under 6 should be supervised when using Sanitizers.

***Other information*** • Store below 110°F (43°C) • May discolor certain fabrics or surfaces.

***Inactive ingredients*** Carbomer, Glycerin, Grapefruit seed extract, Mentha Oil, Propylene glycol, Purified water, Sophora extract, Triethanolamine

Distributed by
**Stronghold Trading, LLC**
5830 Grand Ave, Maspeth, NY 11378

PE

MADE IN CHINA

PFA CERTIFIED

ITM./CAT. 7046-20

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**PFA**

alcohol gel

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:72119-005 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ALCOHOL** (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 100 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE** (UNII: 0A5MM307FC) | |
| **PEPPERMINT OIL** (UNII: AV092KU4JH) | |
| **SOPHORA FLAVESCENS ROOT** (UNII: IYR6K8KQ5K) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **CITRUS PARADISI SEED** (UNII: 12F08874Y7) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:72119-005-02 | 60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/04/2021 | |
| **2** | NDC:72119-005-01 | 2 mL in 1 POUCH; Type 0: Not a Combination Product | 06/04/2021 | |
| **3** | NDC:72119-005-03 | 500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/04/2021 | |
| **4** | NDC:72119-005-04 | 237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/04/2021 | |
| **5** | NDC:72119-005-05 | 375 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 06/04/2021 | |
| **6** | NDC:72119-005-06 | 80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/04/2021 | |
| **7** | NDC:72119-005-07 | 100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/04/2021 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 06/04/2021 | |

## Labeler - BLUE SEA AEROSOL & DAILY CARE CO., LTD (544373091)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| BLUE SEA AEROSOL & DAILY CARE CO., LTD | | 544373091 | manufacture(72119-005) |

Revised: 6/2021 BLUE SEA AEROSOL & DAILY CARE CO., LTD