

AGACHY FAST CLEAN HAND SANITIZER- hand sanitizer gel
ICOMAX 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.

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 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin.

Warnings

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

When using this product do not use in or near the eye. In case of contact with eyes, rinse thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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

Directions

- Place enough product on your palm to cover all surfaces and rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Avoid freezing and excessive heat above 40C (104F)

- May discolor certain fabrics or surface

Inactive ingredients

Water, Butylene Glycol, Glycerin, Carbomer, Triethanolamine, Menthol, Aloe Barbadosis Leaf, Sodium Hyaluronate, 1,2-Hexanediol

Package Label - Principal Display Panel

The image shows the principal display panel of the AGACHY FAST-CLEAN HAND SANITIZER. The top left features the brand name 'AGACHY' and the product name 'FAST-CLEAN HAND SANITIZER' in large, bold letters. Below this, it states 'Kills 99.9% of Germs*' and 'SOOTHING&MOISTURIZING NON-STICKY/WASH FREE'. A red banner across the middle prominently displays '75% ETHANOL' and lists 'Aloe Vera Leaf' and 'Sodium Hyaluronate' as ingredients. The bottom left indicates the volume '500mL /16.90 fl.oz.'. On the right side, there is a detailed 'Drug Facts' panel with sections for Active Ingredient, Use, Warnings, Directions, Other Information, Inactive Ingredients, and Question. At the bottom right, it says 'MADE IN KOREA' with recycling symbols and a barcode.

AGACHY FAST CLEAN HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77201-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	0.01 mL in 100 mL
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	0.0005 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	2 mL in 100 mL
WATER (UNII: 059QF0KO0R)	21.4195 mL in 100 mL

ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.01 mL in 100 mL
LEVOMENTHOL (UNII: BZ1R15MTK7)	0.02 mL in 100 mL
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	0.4 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.14 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77201-001-50	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

Labeler - ICOMAX Co., Ltd. (694834031)

Establishment

Name	Address	ID/FEI	Business Operations
ICOMAX Co., Ltd.		694834031	manufacture(77201-001)

Revised: 5/2020

ICOMAX Co., Ltd.