# HAND SANITIZER- alcohol gel Zhejiang iColor Biotech 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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# Zhejiang iColor Biotech Co., Ltd Hand Sanitizer 1000ml

# Active Ingredient(s)

Ethyl Alcohol 70% v/v.

## **Purpose**

Antiseptic, Hand Sanitizer

#### Use

Hand Sanitizer to help reduce germs on the skin.

## **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: avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Stop using and ask a doctor if irritation or redness develops and lasts.

Keep out of reach of children: ln case of accidental ingestion, get medical help or contact a poison control center immediately.

#### **Directions**

- Squeeze a significant amount in your palm and rub hands until fully dry.
- Rinse free.

#### Other information

• Store below 110 °F043° C).

## **Inactive ingredients**

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl propanol, Aloe Barbadensis leaf Juice, Denatonium benzoate, Fragrance, Glycerin, Maltodextrin, Propylene Glycol, Tocopheryl Acetate, Water.

### Package Label - Principal Display Panel



# **Drug Facts**

## Active ingredient

**Purpose** 

Ethyl Alcohol 70% ...... Antiseptic

Uses: to help reduce germs on the skin.

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  Flammable: Keep away from heat or flame.
  When using this product: avoid contact with eyes.
  If contact occurs, rinse thoroughly with water.
  Stop using and ask a doctor if: irritation or redness develops and lasts.
  Keep out of reach of children: In case of accidental ingestion, get medical help or contact a poison control center immediately.

**Directions:** Squeeze a significant amount in your palm and rub hands until fully dry. Rinse free.

Other information: Store below 110°F (43°C).

### Inactive ingredients:

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aminomethyl propanol, Aloe Barbadensis Leaf Juice, Denatonium benzoate, Fragrance, Glycerin, Maltodextrin, Propylene Glycol, Tocopheryl Acetate, Water.

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Made in China

# HAND SANITIZER

alcohol gel

Droduct	<b>Information</b>
Product	information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:74934-086

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

ı	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

# **Inactive Ingredients**

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
WATER (UNII: 059QF0KO0R)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	
ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

# **Packaging**

I	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1 NDC:74934-086-01	1000 mL in 1 BAG; Type 0: Not a Combination Product	07/22/2020	

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/22/2020		

# Labeler - Zhejiang iColor Biotech Co., Ltd (554528308)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
WESSCO International		118 5536 19	label(74934-086)

Establis	shment
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Lottonomicit				
Name	Address	ID/FEI	Business Operations	
Zhejiang iColor Biotech Co., Ltd		554528308	manufacture(74934-086)	

Revised: 1/2021 Zhejiang iColor Biotech Co., Ltd