

HAND SANITIZER- alcohol gel
ABC INTERNATIONAL

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) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.

Active Ingredient(s)

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

glycerin, vitamin e, aqua, fragrance, trolamine

Package Label - Principal Display Panel



Tue 99% des germes | Anti-Bact'rien
Kills 99% Germs | Anti-Bacterial

Drug Facts: Active ingredient[s]: Purpose

Ethyl Alcohol 70% Antiseptic

Use[s] : Hand rub to reduce bacteria that can potentially cause disease.

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

When using this product keep away from eyes, ears and mouth.

Keep out of reach of children. If swallowed get medical help or call poison control center immediately.

Directions : Place enough product on hands to cover all surfaces. Rub hands together until dry. Children under 6 years old should be supervised when using this product.

Other information: Store at a temperature below 110F (43C)

Inactive ingredient[s] : Aqua, Carbomer, Triethanolamine, Glycerin, Vitamin E & Fragrance.

Faits sur les médicaments : Ingrédient(s) actif(s) : Objectif

Alcool éthylique 70%..... Antiseptique

Utilisation[s] : Frotter-vous les mains pour réduire les microbes qui peuvent potentiellement causer des maladies. **Avertissements :** Pour usage externe uniquement. Inflammable. Tenir loin des flammes ou de la chaleur. **Lorsque vous utilisez ce produit,** gardez-le hors des yeux, des oreilles et de la bouche.

Tenir hors de la portée des enfants. En cas d'ingestion, consultez un médecin ou appelez un centre antipoison immédiatement.

Instructions : Placez suffisamment de produit sur les mains pour couvrir toutes les surfaces. Frottez-vous les mains jusqu'à ce qu'elles soient sèches. Les enfants de moins de 6 ans doivent être surveillés lors de l'utilisation de ce produit.

Autres informations : Conserver à une température inférieure à 43C (110F).

Ingrédient[s] inactif[s] : Aqua, carbomère, triéthanolamine, glycérine vitamine E et parfum

glycerine, vitamin E et paraffin.

5055810001032

H547S

8.4 FL OZ (250ml)

Made in UAE

Questions or comments? :
 contact@bayglobaltrading.com.

Imported By:
Bay Global Trading Corp.
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 West Mississauga, L5B3J1, ON,
 Canada

ABC Industries LLC management system is certified
 as meeting the requirements of **Quality, Environment &**
Good Manufacturing Practices (GMP)
 (ISO 9001: 2008, ISO 14001: 2004 & ISO 22716:2007)

Manufactured By:
ABC Industries LLC.
 Email: inquiry@coolandcool.com
 Website: www.coolandcool.com




Keep Your City Clean

250 mL NDC: 77118-825-25

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77118-825
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	175 mL in 250 mL

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.5 mL in 250 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.05 mL in 250 mL
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 250 mL
TROLAMINE (UNII: 9O3K93S3TK)	1.25 mL in 250 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:77118-825-25	250 mL 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 - ABC INTERNATIONAL (864324525)

Establishment			
Name	Address	ID/FEI	Business Operations
ABC INDUSTRIES LLC		561180632	manufacture(77118-825)

Revised: 8/2020

ABC INTERNATIONAL