

## **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.*

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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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### **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**

250 mL NDC: 77118-824-25



**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.

**W  
47M**

**8.4 FL OZ  
(250ml)**

5055810001278

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Made in UAE

Questions or comments? :

contact@bayglobaltrading.com.

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)

Imported By;

**Bay Global Trading Corp.**

215-350 Burnhamthorpe Road  
West Mississauga, L5B3J1, ON,  
Canada



Manufactured By:

**ABC Industries LLC.**

Email: inquiry@coolandcool.com

Website: www.coolandcool.com



## HAND SANITIZER

alcohol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77118-824
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
TROLAMINE (UNII: 9O3K93S3TK)	1.25 mL in 250 mL
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.5 mL in 250 mL
GLYCERIN (UNII: PDC6A3C0OX)	5 mL in 250 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.05 mL in 250 mL
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77118-824-25	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
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OTC monograph not final	part333A	03/30/2020	
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**Labeler** - ABC INTERNATIONAL (864324525)

**Establishment**

Name	Address	ID/FEI	Business Operations
ABC INDUSTRIES LLC		561180632	manufacture(77118-824)

Revised: 8/2020

ABC INTERNATIONAL