

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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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, trolamine, fragrance, vitamin e, purified water USP

Package Label - Principal Display Panel

60 mL NDC: 77118-860-60



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.

2.02 FL OZ (60ml)
 Imported By:
Bay Global Trading Corp.
 215-350 Burnhamthorpe Road
 West Mississauga, L5B3J1, ON, Canada
Made in UAE

H370S
5060068556005
 Questions or comments? :
 contact@bayglobaltrading.com.

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:77118-860
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	42 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE LEMON ORC2001060 (UNII: K1725A7G95)	0.12 mL in 60 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.2 mL in 60 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.012 mL in 60 mL
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	0.3 mL in 60 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77118-860-60	60 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(77118-860)

Revised: 8/2020

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