

HAND SANITIZER 60ML- alcohol gel
ABC INTERNATIONAL 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.

Cool&Cool Hand Sanitizer Oud 60 ml

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)

Ethyl 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

aqua, Carbopol, PERFUME, VITAMIN E , GLYCERIN, Tri Ethanol Amine

Package Label - Principal Display Panel

60 mL NDC: 77118-905-60



HAND SANITIZER 60ML

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77118-905
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
SILANE, TRIETHENYLMETHYL- (UNII: P423U4YLQ5)	0.3 mL in 60 mL
CARBOPLATIN (UNII: BG3F62OND5)	0.165 mL in 60 mL
PERFLENAPENT (UNII: 483AU1Y5CZ)	0.12 mL in 60 mL
GLYCERIN (UNII: PDC6A3C0OX)	1.2 mL in 60 mL
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	0.015 mL in 60 mL
WATER (UNII: 059QF0K00R)	16.2 mL in 60 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77118-905-60	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	



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.

Made in UAE **H3700DNUS**

2.02 FL OZ
(60ml)

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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 for:
ABC Industries LLC.
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 Shop Online: www.coolandcool.com

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 LTD (864324525)

Establishment

Name	Address	ID/FEI	Business Operations
ABC INDUSTRIES LLC		561180632	manufacture(77118-905)