

HAND SANITIZER 60- 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.

Hand Sanitizer 60ml Ambar

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)

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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

60 mL NDC: 77118-309-60



يحافظ معقم اليدين العنبر كحول أندكول رائحة العنبر الأصلية على حمايتك من البكتيريا والجراثيم الضارة.

Key Features: Cool & Cool Amber Hand Sanitizer with an original Amber aroma keeps you protected from harmful bacteria and germs.

تعليمات الاستعمال: ضع كمية كافية من مطهر اليدين على راحة يدك من ثم افركها بلطف إلى أن تصبح جافة.

Directions: Pour Hand Sanitizer onto the palm of your hand and gently rub.

التحذير: قابل للاشتعال. لاتشرب أو لاتبلع للاستخدام الخارجي فقط. تخزن في مكان بارد وجاف.

Cautions: Flammable. Do not drink or swallow. For external use only. Store in a cool & dry place.

المكونات: الكحول الإيثيلي، ماء، جليسرين، تريثانول إمين، كاربومر، فيتامين إي، عطر.

Ingredients: Ethyl Alcohol, Aqua, Glycerin, Triethanolamine, Carbomer, Fragrance & Vitamin E.

60ml e ٦٠ مل **H1370**

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)

صنع في الإمارات العربية المتحدة
Made in United Arab Emirates

5055810025458

صنع لصالح:
كول اندكول العالمية المحدودة
من قبل: اي بي سي اندستريز ذ.م.م

Trademark owned by
ABC International Ltd.

Manufactured for:
Cool & Cool Int'l Ltd.
By: **ABC Industries LLC.**
Email: inquiry@coolandcool.com
Shop Online: www.coolandcool.com

HAND SANITIZER 60

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77118-309
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
GLYCERIN (UNII: PDC6A3C0OX)	2 mL in 60 mL
1.ALPHA.,24S-DIHYDROXYVITAMIN D2 (UNII: 2900I92Z36)	0.02 mL in 60 mL
WATER (UNII: 059QF0KO0R)	27.48 mL in 60 mL
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.5 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:77118-309-60	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	



يحافظ معقم اليدين العنبر ككول أند ككول برائحة العنبر الأصلية على حمايتك من البكتيريا والجراثيم الضارة.

Key Features: Cool & Cool Amber Hand Sanitizer with an original Amber aroma keeps you protected from harmful bacteria and germs.

تعليمات الاستعمال: ضع كمية كافية من مطهر اليدين على راحة يدك من ثم افركها بلطف إلى أن تصبح جافة.

Directions: Pour Hand Sanitizer onto the palm of your hand and gently rub.

التحذير: قابل للاشتعال. لاتشرب أو لاتبلع للاستخدام الخارجي فقط. تخزن في مكان بارد وجاف.

Cautions: Flammable. Do not drink or swallow. For external use only. Store in a cool & dry place.

المكونات: الكحول الإيثيلي، ماء، جليسرين، تريثانول إمين، كاربومر، فيتامين إي، عطر.

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صنع لصالح: كول اند ككول العالمية المحدودة من قبل: إي بي سي اندستريز ذ.م.م

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By: **ABC Industries LLC.**
Email: inquiry@coolandcool.com
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	api manufacture(77118-309)