

HAND SANITIZER- alcohol gel
MAESA LLC

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.

Keep'Em Clean Instant Hand Sanitizer

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.

Active Ingredient(s)

Alcohol 75% 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

Water, Glycerin, Carbomer, Triethanolamine.

Package Label - Principal Display Panel

29 mL NDC: 71899-102-00



瓶标设计稿确认单

高47mm MC 高47mm

宽23mm FRONT PMS 387C



宽17mm BACK

第五面 第四面 第三面 第二面 第一面

29ml label die cut

<p>Drug Facts (cont'd) fabric surfaces.</p> <p>Inactive Ingredients: Water, Glycerin, Carbomer, Triethanolamine.</p> <p>Questions, Comments: You may report an adverse reaction to: MAESA LLC c/o Report Reaction LLC, PO Box 22, Plainsboro, NJ 08536-0222.</p> <p>DISTRIBUTED BY: MAESA LLC 225 LIBERTY STREET, NEW YORK, NY 10281.</p>	<p>Drug Facts (cont'd) contact a Poison Control Center right away.</p> <p>Directions:</p> <ul style="list-style-type: none"> • Put enough product in your palm to cover hands and rub hands together until dry. • Children under 6 years of age should be supervised when using this product. <p>Other Information:</p> <ul style="list-style-type: none"> • Store between 59 - 86°F (15 - 30°C). • Avoid freezing and excessive heat above 104°F (40°C). • May discolor certain 	<p>Drug Facts (cont'd)</p> <ul style="list-style-type: none"> • Keep away from fire or flame. • For external use only. • Do not use in children less than 2 months of age. • On open skin wounds. • When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water. Stop use and ask doctor if irritation or rash appears and lasts. • Keep out of reach of children. • If swallowed, get medical help or 	<p>PEEL</p> <p>TRUSTED FORMULA. KILLS 99.9% OF GERMS AND BACTERIA.</p> <p>Drug Facts: Alcohol 75% v/v</p> <p>Purpose Antiseptic</p> <p>Uses:</p> <ul style="list-style-type: none"> • Hand sanitizer to help reduce bacteria that potentially can cause disease. • For use when soap and water are not available. <p>Warnings:</p> <ul style="list-style-type: none"> • Flammable.
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瓶标

客户:		产品型号		名称有无注册	
设计稿名称	瓶标	尺寸	正标: 23*47mm	背标: 17*47mm	
纸张	正标: 白色PE	背标: 合成材料			
工艺	 PMS 387C	 印黑	亮光	左右出标	
设计专员	罗泉	打印日期	2020.4.15	业务员签字	签字日期

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71899-103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	21.75 mL in 29 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	0.0725 mL in 29 mL
WATER (UNII: 059QF0KO0R)	
CARBOMER 940 (UNII: 4Q93RCW27E)	0.1305 mL in 29 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.29 mL in 29 mL

Product Characteristics

Color	white (Transparent)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71899-103-00	29 mL in 1 PACKET; Type 0: Not a Combination Product	05/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/22/2020	

Labeler - MAESA LLC (144282311)

Revised: 6/2020

MAESA LLC