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.

Caught Clean Handed 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: 71899-107-00



瓶标

客户:	_]	产品型号	10-193-A	RO-0281	名称有无注册		
设计稿名称	瓶标		尺寸	正标: 23	3*47mm	背标: 17*47mm	
纸张	正标:	白色PE	背标: 合成	材料			
工艺	P.A	ANTONE 23	2C	印黑		亮光	左右出标
设计专员	罗泉	打印日期	2020.6.20	业务员签字		签字日期	

HAND SANITIZER					
alcohol gel					
Product Information	Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71899-107		
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				

ı	Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 N	NDC:71899-107-00	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: 7/2020 MAESA LLC