HAND SANITIZER- alcohol liquid GUANGDONG HAOSHUN ODIS TECHNOLOGY COMPANY LIMITED

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.

Archele Disenfectant Spray EA 75%

Information

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 & Purpose

Antiseptic, Hand Sanitizer

Actove ingredient	Purpose
Alcohol 75% v/v	Antiseptic

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.

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, chlorhexidine gluconate, purified water USP

Package Label - Principal Display Panel

180 mL NDC: 74895-104-01



印刷产品设计/变更确认稿





AR-8002

NET WEIGHT: 180ml



批准 logo商标 产品规格 外语翻译

制作工艺 企业信息 包装材质 配套物料 产品说明 使用方法 注意事项 版面标识 执行标准 条码二维码

包装尺寸

注:本打印稿颜色仅供参考实际以上机印刷为准,各部门根据表格仔细核对所属内容,正确无误后打√,如纸稿内容无表格项则留空, 高清电子版在共享设计目录里, 本纸稿一式两份,一份留质检部作为来料检验标准,一份留采购部存档作为采购标准、 纸稿需经以上部门全部亲笔签名后方可生效,各部门需及时审核并流转, 保障流程畅顺。

HAND SANITIZER

alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74895-104
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6 A3C0 OX)	0.5 mL in 100 mL	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	2.5 mL in 100 mL	
WATER (UNII: 059QF0KO0R)		

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:74895-104	180 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/05/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/05/2020	

Labeler - Guangdong Haoshun odis Technology Company Limited (547109432)

Revised: 1/2021 GUANGDONG HAOSHUN ODIS TECHNOLOGY COMPANY LIMITED