

HAND SANITIZER- alcohol gel
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 HS Gel EA 80 %

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:

- 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 ingredients & Purpose

Antiseptic, Hand Sanitizer

Active ingredient

Alcohol 80% v/v

Purpose

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, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

80 mL NDC: 74895-101-01



印刷产品设计/变更确认稿

制作人：梁海健

顾客名称：爱车乐英文	产品名称：8001手部速干消毒液80mL	材质：软管 φ35(109)x130mm	编号：SJ-ACL-RG-8193-1.0
尺寸：107X130mm(跟样板)	印刷：C M Y K	配套：无	制作日期：2020.3.19

107mm

130mm

120mm

封尾5mm
留空2mm

留空3mm

新增K3代码：否 是：_____

部门	项目	审核	批准
设计部	文件尺寸		
	颜色标识		
	材质标识		
需求部门	包装风格		
	产品名称		
	logo商标		
	产品规格		
	外语翻译		
	制作工艺		
	企业信息		
	包装材质		
技术部	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			

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480 mL NDC: 74895-101-02



顾客名称: 爱车乐英文	产品名称: 8004手部速干消毒液480mL	材质: 艾利纸光膜	编号: SJ-ACL-TZ-8196-1.0
尺寸: 37x100mm	印刷: CMYK	配套:	制作日期: 2020.3.19



新增K3代码: 否 是 :

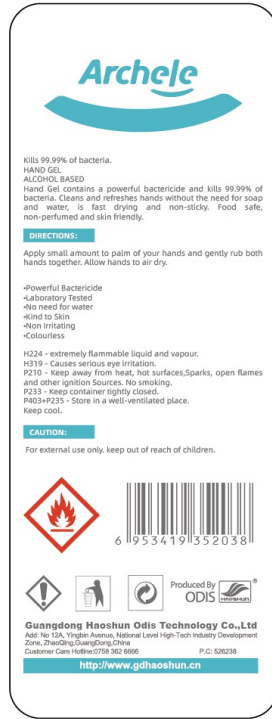
部门	项目	审核	批准
设计部	文件尺寸		
	颜色标识		
	材质标识		
需求部门	包装风格		
	产品名称		
	logo商标		
	产品规格		
	外语翻译		
	制作工艺		
	企业信息		
	包装材质		
技术部	配套物料		
	产品说明		
	使用方法		
	注意事项		
	版面标识		
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	条码二维码		
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290 mL NDC: 74895-101-03



顾客名称: 爱车乐英文	产品名称: 8003手部速干消毒液290mL	材质: 艾利纸光膜	编号: SJ-ACL-TZ-8195-1.0
尺寸: 30x80mm	印刷: CMYK	配套:	制作日期: 2020.3.19



新增K3代码: 否 是

部门	项目	审核	批准
设计部	文件尺寸		
	颜色标识		
	材质标识		
需求部门	包装风格		
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	制作工艺		
	企业信息		
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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74895-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74895-101-01	80 mL in 1 TUBE; Type 0: Not a Combination Product	04/07/2020	
2	NDC:74895-101-03	290 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/07/2020	
3	NDC:74895-101-02	480 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/07/2020	
4	NDC:74895-101-04	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/24/2020	
5	NDC:74895-101-05	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/07/2020	

Labeler - GUANGDONG HAOSHUN ODIS TECHNOLOGY COMPANY LIMITED (547109432)

Revised: 1/2021

GUANGDONG HAOSHUN ODIS TECHNOLOGY COMPANY LIMITED