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.

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 80% 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

74895-102-02



印刷产品设计/变更确认稿





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印刷产品设计/变更确认稿



文件尺寸 颜色标识 材质标识 包装风格 产品名称 logo商标

宙核

批准

项目

编号:SJ-ACL-GZ-8255-1.0

制作日期: 2020.3.28

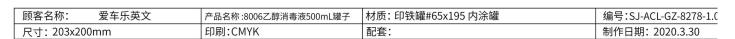
产品规格 外语翻译 制作工艺 企业信息 包装材质 配套物料 产品说明 使用方法 注意事项 版面标识 执行标准 条码二维码 包装尺寸

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74895-102-04



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74895-102-05



印刷产品设计/变更确认稿





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	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				
		配套物料				
	技术部	产品说明				
		使用方法				
		注意事项				
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HAND SANITIZER

alcohol liquid

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:74895-102

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)
ALCOHOL (UNII: 3K9958V90M) ALCOHOL 80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74895-102- 02	180 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/08/2020	
2	NDC:74895-102- 03	450 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/08/2020	
3	NDC:74895-102- 04	500 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/08/2020	
4	NDC:74895-102- 05	650 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/08/2020	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	04/08/2020			

Labeler - Guangdong Haoshun odis Technology Company Limited (547109432)

Registrant - Guangdong Haoshun odis technology company limited (547109432)

Establishment				
Name	Address	ID/FEI	Business Operations	
GUANGDONG HAOSHUN ODIS TECHNOLOGY COMPANY LIMITED		547109432	manufacture(74895-102), pack(74895-102), label(74895-102)	

Revised: 4/2020 GUANGDONG HAOSHUN ODIS TECHNOLOGY COMPANY LIMITED