

HAND SANITIZER- alcohol cloth
MRMB HOME 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.

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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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

80ct NDC: 74346-8051-1

HAND SANITIZER

KILLS 99.9% OF BACTERIA*

SPENCER HEALTH

SANITIZER WIPES

KILLS 99.9% OF BACTERIA*

CONTAINS 75% ALCOHOL

80 Wipes
6 inch x 8 inch
(15x20cm)

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SPENCER HEALTH

SANITIZER WIPES

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DRUG FACTS

Active Ingredient	Purpose
Ethyl Alcohol 75% v/v.....	Antiseptic
Uses: To clean, sanitize, and disinfect the skin.	
Directions: Remove lid from container. Find center of wipe roll, remove first wipe for use, peel center of each wipe into container, and dispense as needed. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep lid closed to prevent moisture loss.	
Inactive Ingredients: Water	
WARNINGS For external use only. Flammable. Keep away from heat or flame.	
WHEN USING THIS PRODUCT keep out of eyes, ears and mouth. In case of contact with eyes, rinse 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.	
OTHER INFORMATION	
<ul style="list-style-type: none"> • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) 	

THE EASY WAY TO CLEAN AND SANITIZE HANDS.

Empty & Replace Cap

PLASTIC BOTTLE

DISTRIBUTED BY:
SPENCER HEALTH LLC
82 MAIN ST. SAG HARBOR
CEDARPOINT HOLDINGS PTY. LTD.
3C, 27 JAMES ST.
BURLINGHAM HEADS
GLASGOW, SCOTLAND
MADE IN CHINA

SPENCER HEALTH



alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74346-8051
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	18000 cm2 in 24000 cm2

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74346-8051-1	24000 cm2 in 1 CANISTER; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - MRMB HOME LLC (128031530)

Revised: 10/2020

MRMB HOME LLC