

C19 ANTIMICROBIAL HAND SANITIZER- alcohol gel
Kabana Skin Care 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.

ACTIVE INGREDIENT

Ethyl Alcohol 70% v/v.

PURPOSE

Antimicrobial

USE

Hand Sanitizer to help reduce pathogens on the skin.

WARNINGS

FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME.

THIS PRODUCT IS INTENDED FOR EXTERNAL USE ONLY.

DISCONTINUE USE IF irritation or redness develops.
If condition persists for more than 72 hours, consult a doctor.

Do not use

DISCONTINUE USE IF irritation or redness develops.

If condition persists for more than 72 hours, consult a doctor.

WHEN USING THIS PRODUCT, Do not use in or near the eyes.

In case of contact, 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 in your palm to thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

- Store below 110F (44C)
- May discolor certain fabrics or surfaces

INACTIVE INGREDIENTS

Water (aqua), Hydroxyethylcellulose

Package Label



DRUG FACTS	
ACTIVE INGREDIENT	PURPOSE
ETHYL ALCOHOL, 70% V/V	ANTIMICROBIAL
USE HAND SANITIZER TO HELP REDUCE PATHOGENS ON THE SKIN	
WARNINGS	
FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME. THIS PRODUCT IS INTENDED FOR EXTERNAL USE ONLY. WHEN USING THIS PRODUCT, DO NOT USE IN OR NEAR THE EYES. IN CASE OF CONTACT, RINSE EYES THOROUGHLY WITH WATER. DISCONTINUE USE IF IRRITATION OR REDNESS DEVELOPS. IF IRRITATION PERSISTS FOR MORE THAN 72 HOURS, CONSULT A DOCTOR. KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP OR CONTACT A POISON CENTER RIGHT AWAY.	
DIRECTIONS	
• PLACE ENOUGH PRODUCT IN YOUR PALM TO THOROUGHLY COVER YOUR HANDS • RUB HANDS TOGETHER BRISKLY UNTIL DRY • CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED WHEN USING THIS PRODUCT	
OTHER INFORMATION	
• STORE BELOW 110°F (34°C) • MAY DISCOLOR CERTAIN FABRICS OR SURFACES	
INACTIVE INGREDIENTS	
WATER (AQUA), HYDROXYETHYLCELLULOSE	
KABANA ONLY USES 200 PROOF FOOD GRADE ETHYL ALCOHOL, FREE OF NEUROTOXIC DENATURANTS	
MADE IN THE USA 888.517.0414 9-5 MST MANUFACTURED BY KABANA SKIN CARE IN COLORADO WWW.KABANASKINCARE.COM	

C19 ANTIMICROBIAL HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73369-0009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	64.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	1.2 g in 100 g
WATER (UNII: 059QF0KO0R)	34.1 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73369-0009-1	78 g in 1 TUBE; Type 0: Not a Combination Product	04/03/2020	
2	NDC:73369-0009-2	206 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/03/2020	
3	NDC:73369-0009-4	3359 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	
4	NDC:73369-0009-3	822 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/03/2020	

Labeler - Kabana Skin Care LLC (080237112)

Registrant - Kabana Skin Care LLC (080237112)

Establishment

Name	Address	ID/FEI	Business Operations
Kabana Skin Care LLC		080237112	manufacture(73369-0009)

Revised: 10/2023

Kabana Skin Care LLC