# HAND SANITIZER- alcohol gel DERMACK SAS

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.

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#### **HANDS SANITIZER 70%**

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.

Alcohol 70% 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, Trolamine (Triethanolamine), Aloe Vera Leaf (Aloe Barbadensis leaf extract), Carbomer 940, purified water USP

#### Package Label - Principal Display Panel



1000 L NDC: 80232-001-01

# HAND SANITIZER alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:80232-001 Route of Administration TOPICAL Active Ingredient/Active Moiety

**Basis of Strength** 

ALCOHOL

Strength

700 L in 1000 L

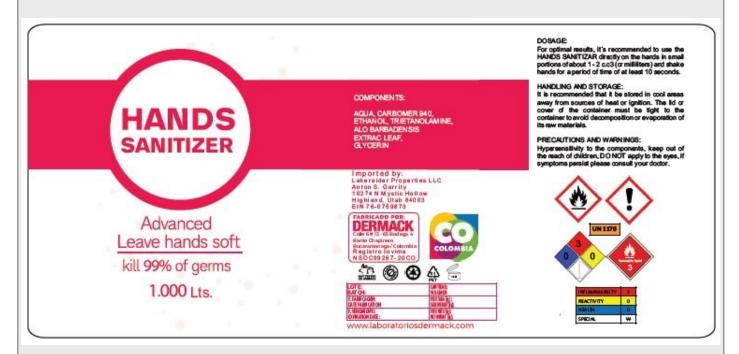
**Ingredient Name** 

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)	14.5 L in 1000 L			
CARBOMER 940 (UNII: 4Q93RCW27E)	2.5 L in 1000 L			
TROLAMINE (UNII: 903K93S3TK)	2 L in 1000 L			
WATER (UNII: 059QF0KO0R)	274 L in 1000 L			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	7 L in 1000 L			

Product Characteristics		
Color	Score	
Shape	Size	
Flavor	Imprint Code	
Contains		

l	Packaging				
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
l	1 NDC:80232-001-01	1000 L in 1 TANK; 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 - DERMACK SAS (884605822)

# **Registrant - DERMACK SAS (884605822)**

## **Establishment**

Name	Address	ID/FEI	Business Operations
DERMACK SAS		884605822	manufacture(80232-001)

Revised: 8/2020 DERMACK SAS