

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.

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

HANDS SANITIZER

Advanced
Leave hands soft
kill 99% of germs
1.000 Lts.

COMPONENTS:
AGUA, CARBOMER 940,
ETHANOL, TRIETANOLAMINE,
ALO BARBADENSIS
EXTRAC LEAF,
GLYCERIN

Imported by:
Lake Rider Properties LLC
Anton S. Garrity
10274 N Mystic Hollow
Highland, Utah 84003
EIN 76-0759873

FABRICADO POR:
DERMACK
Calle 64 32 - 65 Insurg 4
Barrio Chapinero
Bucaramanga / Colombia
Registado en VIMA
N.S.O. C99 26 T- 20 CO

UN 1170

0	3	0	3
INFLAMMABILITY: 3		REACTIVITY: 0	
HEALTH: 0		SPECIAL: W	

www.laboratoriosdermack.com

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

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	700 L in 1000 L

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: 9O3K93S3TK)	2 L in 1000 L
WATER (UNII: 059QF0K00R)	274 L in 1000 L
ALOE VERA LEAF (UNII: ZY81Z83H0X)	7 L in 1000 L

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80232-001-01	1000 L in 1 TANK; Type 0: Not a Combination Product	03/30/2020	

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DOSAGE:
For optimal results, it's recommended to use the HANDS SANITIZER directly on the hands in small portions of about 1-2 cc3 (or milliliters) and shake hands for a period of time of at least 10 seconds.

HANDLING AND STORAGE:
It is recommended that it be stored in cool areas away from sources of heat or ignition. The lid or cover of the container must be tight to the container to avoid decomposition or evaporation of its raw materials.

PRECAUTIONS AND WARNINGS:
Hypersensitivity to the components, keep out of the reach of children, DO NOT apply to the eyes, if symptoms persist please consult your doctor.

UN 1170

INFLAMMABILITY	3
REACTIVITY	0
HAZARD	0
SPECIAL	W

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