

SANIDRY- alcohol solution
QUIMICA ROSMAR S.A. DE C.V.

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

200 L (2000 mL) NDC: 77251-001-01



SANIDRY

ALCOHOL ANTISEPTIC 80%

Drug Facts	
Active Ingredient Ethyl Alcohol 80% v/v	Purpose Antimicrobial
Uses Hand sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.	
Warnings Flammable. Keep away from source of heat, fire or flame. For external use only. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask a doctor if irritation or redness develops and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions <ul style="list-style-type: none">Place enough product in your palm to thoroughly cover your hands and rub hands together until dry.Children under 6 years should be supervised when using this product.	
Inactive Ingredients glycerin, hydrogen peroxide, purified Water (Aqua)	
Directions <ul style="list-style-type: none">Store at temperature below 110 °F (43 °C)May discolor certain fabrics or surfaces	

Topical Solution

**HAND SANITIZER
NON-STERILE SOLUTION**

Made in Mexico by/ Hecho en México por
Química Rosmar, SA de CV
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*Etiquetado para uso fuera de territorio mexicano

NDC 77251-001-01

NOT LABELED FOR INDIVIDUAL SALE

It is a violation of Federal law to use this product in
a manner inconsistent with its labeling.

NET CONTENTS: 52.83 gal (200 Liter)

SANIDRY

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77251-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0KO0R)	18.425 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77251-001-01	200 L in 1 PAIL; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

Labeler - QUIMICA ROSMAR S.A. DE C.V. (814223475)**Establishment**

Name	Address	ID/FEI	Business Operations
QUIMICA ROSMAR S.A. DE C.V.		814223475	manufacture(77251-001)

Revised: 5/2020

QUIMICA ROSMAR S.A. DE C.V.