

**SANIDRY- alcohol cloth**  
**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.*

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**77251-006 Sanidry**  
**Alcohol 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.

**Active Ingredient(s)**

Alcohol 70% v/v. Purpose: Antiseptic

**Purpose**

Antiseptic, Hand Sanitizer

**Use**

For hand sanitizing to decrease bacteria on the skin when water and soap are not available.

Recommended for repeated use.

**Warnings**

For external use only. Flammable. Keep away from fire or flame

**Do not use**

- Do not use near eyes.

When using this product, do not use near eyes. If contact occurs, flush thoroughly with water.

Stop use and contact a doctor if irritation or redness persists for more than 72 hours

Keep out of reach of children unless under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- Remove wipes
- Rub hands together briskly until dry. No rinsing required.
- Do not reuse the towel, dispose of it immediately after use.

## Other information

- Store at temperature below 110F(43C)
- Do not puncture or incinerate container

## Inactive ingredients

purified water USP, glycerin

## Package Label - Principal Display Panel

300 units NDC: 77251-006-01

**Drugs Facts**

**Active Ingredient**  
Ethyl Alcohol 70% (v/v).....Antiseptic

**Uses**  
 ■ For hand sanitizing to decrease bacteria on the skin when water and soap are not available.  
 ■ Recommended for repeated use.

**Warnings**  
 For external use only. Flammable: keep away from fire or flame.  
 When using this product do not use near eyes.  
 If contact occurs, flush thoroughly with water.  
 Stop use and contact a doctor if irritation or redness persists for more than 72 hours.  
 Keep out of reach of children unless under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**  
 ■ Remove wipes.  
 ■ Rub hands together briskly until dry. ■ No rinsing required.  
 ■ Do not reuse the towel, dispose of it immediately after use.

**Other Information**  
 ■ Store at temperature below 110 F. (43°C)  
 ■ Do not puncture or incinerate container.

**Inactive Ingredients** purified water USP, glycerine.

**SANIDRY<sup>®</sup> Dry cleaning Wipes**

**70% ALCOHOL BASED**

**300 Wipes**

Hand sanitizer wipes  
 For sanitizing & bacteria decreasing  
 Does not dry out, irritate or leave residues  
 Unscented

NET CONTENTS: 300 wipes 5.9 IN x 6.7 IN (15 cm x 17 cm)

## SANIDRY

alcohol cloth

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77251-006
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
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GLYCERIN (UNII: PDC6A3C00X)

WATER (UNII: 059QF0K00R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77251-006-01	1275 mL in 1 BAG; Type 0: Not a Combination Product	01/04/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/04/2021	

**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(77251-006)

Revised: 1/2021

QUIMICA ROSMAR S.A. DE C.V.