

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.

77251-007 Sanidry
Hydrogen Peroxide 3 %

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)

Hydrogen peroxide 3% v/v. Purpose: First Aid Antiseptic

Purpose

First Aid Antiseptic

Use

As an antiseptic to help prevent infection in minor cuts, scrapes, burns.

Warnings

For external use only.

Do not use

Do not use in the eyes or apply over large areas of the body

Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns.

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.

Stop use

- if the condition persists or gets worse
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

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

Directions

- Clean the affected area
- Remove wipes
- Rub together briskly until dry
- No rinsing required
- Do not reuse the towel, dispose immediately after use.

Other information

- Do not apply internally
- Store at temperature below 110F(43C)
- Hold away from face when opening

Inactive ingredients

purified water

Package Label - Principal Display Panel

300 units NDC: 77251-007-01

Drugs Facts

Active Ingredient
Hydrogen peroxide 3%.....First Aid Antiseptic

Uses
■ As an antiseptic to help prevent infection in minor cuts, scrapes, burns.

Warnings
For external use only.
Do not use in the eyes or apply over large areas of the body
Ask a doctor before use if you have deep or puncture wounds, animal bites or serious burns.

Stop use
■ If the condition persists or gets worse
■ Irritation, pain, or redness persists or worsens
■ Swelling, rash or fever develops

Keep out or reach children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Inactive Ingredients purified water.

Other Information
■ Do not apply internally. ■ Store at temperature below 110 F (43°C) ■ hold away from face when opening.

SANIDRY[®] Peroxi

Wipes

First Aid Antiseptic

SANITIZING

KILLS 99.9% OF ILLNESS CAUSING GERMS

300 Wipes

Hydrogen peroxide wipes
For sanitizing & bacteria decreasing
Does not dry out, irritate or leave residues
Rinse-free

rosmar USA

Made in Mexico
Química Rosmar, S.A. de C.V.
Carretera de los Vivientes No. 40,
Mexico City, Quimica Rosmar®.
All Rights Reserved.

*Etiquetado para uso fuera de territorio mexicano.

Labeled for use outside Mexican Territory.

CONSUMER LINE
Questions? Comment?
Call 1-833-4-ROSMAR
Or check www.rosmar-usa.com

NOT LABELED FOR INDIVIDUAL SALE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

NDC 77251-007-01

7 503030 502542

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

SANIDRY

alcohol cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77251-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	3 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77251-007-01	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(77251-007)

Revised: 1/2021

QUIMICA ROSMAR S.A DE C.V