

SANIDRY- hand sanitizer gel gel
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.

77251-003 Sanidry Hand Sanitizer

Active ingredient

Ethyl Alcohol 70% (v/v)

Purpose

Antiseptic

Uses

- Hand sanitizing to help reduce bacteria on the skin that potentially can cause disease.
- For use when soap and water are not available

Warnings

☐For external use only. Flammable: keep away from fire or flame.

When using this product

☐Do not use

- on children less than 2 months.
- on open skin wounds.

Stop use and ask 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

- Place enough product in your palm to thoroughly cover hands
- Rub hands together briskly until dry
- No rinsing required
- No towels needed

Other information

- Store at temperature below 110 F (43°C)
- May discolor certain fabrics or surfaces

Inactive ingredients

carbomer, glycerin, triethanolamine, purified water USP.

250 mL - NDC 77251-003-01

SANIDRY[®]
Hand Sanitizer Gel
70% ALCOHOL BASED

KILLS 99.99% OR MOST COMMON GERMS THAT CAUSE ILLNESS

Non sticky formula
Leaves hands feeling soft

UNSCENTED

Net content: 8.4oz (250ml)

Drugs Facts

Active ingredient(s)
Ethyl Alcohol (70% (v/v)) Antiseptic

Use(s)
■ Hand sanitizing to help reduce bacteria on the skin that potentially can cause disease.
■ For use when soap and water are not available.

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

When using this product
DO NOT USE
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■ on open skin wounds.

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Directions
■ Place enough product in your palm to thoroughly cover hands. ■ Rub hands together briskly until dry. ■ No rinsing required. ■ No towels needed.

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Inactive ingredients carbomer, glycerin, triethanolamine, purified water USP.

NDC 77251 - 003 - 01 Rosmar[®] and Sandry[®] are trademark or registered trademark of Quimica Rosmar, SA de CV. © All Rights Reserved. "Etiquetado para uso fuera de territorio mexicano. It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Made in Mexico by Hecho en México por Quimica Rosmar, SA de CV Camino de los Vientos No. 45, Mexico Grande Maris Toluca, Toluca, Tlaxcala, 02670, MEXICO +5255-3004-2820

7 503030 502016

236 mL - NDC 77251-003-02



SANIDRY

Hand Sanitizer Gel

HAND SANITIZER GEL
KILLS 99.99% of germs

LOT: #####
EXP: ##/####

NET CONTENTS: 8oz (236 mL)

500 mL - NDC 77251-003-03

Drugs Facts
Active ingredient Ethyl Alcohol 70% (v/v) Antiseptic
Uses •Hand sanitizing to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are not available.
Warnings For external use only. Flammable: keep away from fire or flame. When using this product Do not use •on children less than 2 months. •on open skin wounds. 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 •Place enough product in your palm to thoroughly cover hands •Rub hands together briskly until dry •No rinsing required •No towels needed
Other information •Store at temperature below 110 F (43°C) •May discolor certain fabrics or surfaces
Inactive ingredients carbomer, glycerin, triethanolamine, purified water USP.

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Química Rosmar, SA de CV
Camino de Los Viveros No. 49, Mexico (Santa Maria Tomatlan, Iztapalapa),
09870. MEXICO
+52 55 3004 2820

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NDC 77251 - 003 -02

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Hand Sanitizer Gel
 70% ALCOHOL BASED

KILLS 99.99%
 OF MOST COMMON GERMS
 THAT MAY CAUSE ILLNESS

Non sticky formula
 Leaves hands feeling soft

UNSCENTED

Net content: 16.9oz (500ml)

Drugs Facts

Active Ingredient[s]

Ethyl Alcohol 70%(w/v)..... Antiseptic

Use[s]

- Hand sanitizing to help reduce bacteria on the skin that potentially can cause disease.
- For use when soap and water are not available.

Warnings

For external use only. Flammable: keep away from fire or flame.

When using this product

Do not use

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- on open skin wounds.

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Directions

- Place enough product in your palm to thoroughly cover hands
- Rub hands together briskly until dry • No rinsing required
- No towels needed

Other information

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Inactive ingredients carbomer, glycerin, triethanolamine, purified water USP.

NDC 77251-003-03

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1000 mL - NDC 77251-003-04

SANIDRY®
Hand Sanitizer Gel
70% ALCOHOL BASED

KILLS 99.99%
 OF MOST COMMON GERMS
 THAT MAY CAUSE ILLNESS

Non sticky formula

Leaves hands feeling soft

UNSCENTED

Net content: 33.8oz (1,000ml)

Drugs Facts

Active Ingredient[s]

Ethyl Alcohol 70%(V/V).....Antiseptic

Use[s]

- Hand sanitizing to help reduce bacteria on the skin that potentially can cause disease.
- For use when soap and water are not available.

Warnings

For external use only. Flammable: keep away from fire or flame.

When using this product

Do not use

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- Rub hands together briskly until dry
- No rinsing required
- No towels needed

Other Information

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Inactive Ingredients carbomer, glycerin, triethanolamine, purified water USP.

NDC 77251 - 003- 04

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4000 mL - NDC 77251-003-05



SANIDRY

Hand Sanitizer Gel

HAND SANITIZER GEL
KILLS 99.99% of germs

LOT: #####
EXP: ##/####

NET CONTENTS: 4000 mL (4 L)

20 L - NDC 77251-003-06

Drugs Facts
Active ingredient Ethyl Alcohol 70% (v/v) Antiseptic
Uses •Hand sanitizing to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are not available.
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SANIDRY

Hand Sanitizer Gel

HAND SANITIZER GEL
KILLS 99.99% of germs

LOT: #####
EXP: ##/####

NET CONTENTS: 20,000 mL (20 L)

200 L- NDC 77251-003-07

Drugs Facts
Active ingredient Ethyl Alcohol 70% (v/v) Antiseptic
Uses •Hand sanitizing to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are not available.
Warnings For external use only. Flammable: keep away from fire or flame. When using this product Do not use •on children less than 2 months. •on open skin wounds. 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.
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Inactive ingredients carbomer, glycerin, triethanolamine, purified water USP.

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SANIDRY

Hand Sanitizer Gel

HAND SANITIZER GEL
KILLS 99.99% of germs

LOT: #####
 EXP: ##/####

Drugs Facts
Active ingredient Ethyl Alcohol 70% (v/v) Antiseptic
Uses <ul style="list-style-type: none"> •Hand sanitizing to help reduce bacteria on the skin that potentially can cause disease. •For use when soap and water are not available.
Warnings For external use only. Flammable: keep away from fire or flame. When using this product Do not use <ul style="list-style-type: none"> •on children less than 2 months. •on open skin wounds. 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 <ul style="list-style-type: none"> •Place enough product in your palm to thoroughly cover hands •Rub hands together briskly until dry •No rinsing required •No towels needed
Other information <ul style="list-style-type: none"> •Store at temperature below 110 F (43°C) •May discolor certain fabrics or surfaces
Inactive ingredients carbomer, glycerin, triethanolamine, purified water USP.

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NET CONTENTS: 200,000 mL (200 L)

SANIDRY			
hand sanitizer gel gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77251-003
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 L in 100 L
Inactive Ingredients			
	Ingredient Name	Strength	
	CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)		
	GLYCERIN (UNII: PDC6A3C0OX)		
	TROLAMINE (UNII: 9O3K93S3TK)		
	WATER (UNII: 059QF0KO0R)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77251-003-01	0.25 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/05/2020	
2	NDC:77251-003-02	0.236 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/05/2020	
3	NDC:77251-003-03	0.5 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/05/2020	
4	NDC:77251-003-04	1 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/05/2020	
5	NDC:77251-003-05	4 L in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2020	
6	NDC:77251-003-06	20 L in 1 PAIL; Type 0: Not a Combination Product	06/05/2020	
7	NDC:77251-003-07	200 L in 1 DRUM; Type 0: Not a Combination Product	06/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/05/2020	

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(77251-003)

Revised: 12/2020

QUIMICA ROSMAR S.A. DE C.V.