

NEUTROGEL- soap 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.

77251-008 Neutrogel
Benzethonium chloride 0.10 %

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)

Benzethonium chloride 0.10% w/w. Purpose: Antiseptic

Purpose

Antiseptic

Use

- For washing sanitizing hands
- Helps reduce bacteria on the skin that potentially can cause disease

Warnings

For external use only.

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product do not use

- On children less than 2 months of age
- 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. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet as needed
- Place enough product in your hand
- Rub gently for at least 30 seconds
- Wash skin, rinse thoroughly and dry

Other information

- Store at temperature below 110F (43C)

Inactive ingredients

water, sodium lauryl ether sulfate, cocamidopropyl betaine, cocamide DEA, glycerin, propylene glycol, sodium chloride, citric acid, DMDM hydantoin

Package Label - Principal Display Panel

Colores:

C: 74	
M: 40	
Y: 30	
K: 13	
C: 90	
M: 52	
Y: 44	
K: 38	
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	

NEUTROGEL®

Antibacterial Soap

KILLS 99.9% OF BACTERIA AND VIRUSES*

No dry or irritated skin

Residue free

Unscented

NETWT 135.2oz (4L)

Fecha: 02 de diciembre 2020

Documento: Etiqueta NEUTROGEL 4L

Cliente: Química Rosmar

Observaciones: Favor de presentar prueba de color en cuatricromía

4000 mL NDC: 77251-008-01

20000 mL NDC: 77251-008-02

20000 mL NDC : 77251-008-03

Colores:

C:	74
M:	40
Y:	30
K:	13
C:	90
M:	52
Y:	44
K:	38
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	

Drugs Facts

Active ingredient **purpose**
Benzethonium chloride 0.10% (w/w)..... Antiseptic

Uses
•For washing sanitizing hands.
•Help to reduce bacteria on the skin that potentially can use disease.

Warnings
For external use only.

When using this product
Do not use
•On children less than 2 months of age.
•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
•Wet as needed • Place enough product in your hand
•Rub gently for at least 30 seconds.
•Wash skin, rinse thoroughly and dry.

Other information
•Store at temperature below 110 F (43°C)

Inactive ingredients water (aqua), sodium lauryl ether sulfate, cocamidopropyl betaine, cocamide DEA, glycerin, propylene glycol, sodium chloride, citric acid, DMDM hydantoin.

MADE IN MEXICO
Química Rosmar, S.A. de C.V.
Carretera de los Volcanes No. 40
Mexico City.

NDC 77251-008-05

rosmar USA

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

7 503030 502849

NEUTROGEL®

Antibacterial Soap

KILLS 99.9% OF BACTERIA AND VIRUSES*

No dry or irritated skin

Residue free

Unscented

NETWT 676.2oz (20L)

Fecha: 02 de diciembre 2020

Documento: Etiqueta
NEUTROGEL 20L

Cliente: Química Rosmar

Observaciones: Favor de presentar prueba de color en cuatricromía

1000 mL NDC: 77251-008-04

Colores:

C:	74
M:	40
Y:	30
K:	13
C:	90
M:	52
Y:	44
K:	38
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	

Drugs Facts

Active ingredient **purpose**
Benzethonium chloride 0.10% (w/w)..... Antiseptic

Uses
•For washing sanitizing hands.
•Help to reduce bacteria on the skin that potentially can use disease.

Warnings
For external use only.

When using this product
Do not use
•On children less than 2 months of age.
•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
•Wet as needed • Place enough product in your hand
•Rub gently for at least 30 seconds.
•Wash skin, rinse thoroughly and dry.

Other information
•Store at temperature below 110 F (43°C)

Inactive ingredients water (aqua), sodium lauryl ether sulfate, cocamidopropyl betaine, cocamide DEA, glycerin, propylene glycol, sodium chloride, citric acid, DMDM hydantoin.

MADE IN MEXICO
Química Rosmar, S.A. de C.V.
Carretera de los Volcanes No. 40
Mexico City.

NDC 77251-008-03

rosmar USA

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

7 503030 502897

NEUTROGEL®

Antibacterial Soap

KILLS 99.9% OF BACTERIA AND VIRUSES*

No dry or irritated skin

Residue free

Unscented

NETWT 33.8oz (1000ml)

Fecha: 02 de diciembre 2020

Documento: Etiqueta
NEUTROGEL 1000 ml

Cliente: Química Rosmar

Observaciones: Favor de presentar prueba de color en cuatricromía

500 mL NDC: 77251-008-05

Colores:

<input type="checkbox"/>	C:	74
<input type="checkbox"/>	M:	40
<input type="checkbox"/>	Y:	50
<input type="checkbox"/>	K:	13
<input type="checkbox"/>	C:	90
<input type="checkbox"/>	M:	52
<input type="checkbox"/>	Y:	44
<input type="checkbox"/>	K:	38
<input type="checkbox"/>	C:	
<input type="checkbox"/>	M:	
<input type="checkbox"/>	Y:	
<input type="checkbox"/>	K:	
<input type="checkbox"/>	C:	
<input type="checkbox"/>	M:	
<input type="checkbox"/>	Y:	
<input type="checkbox"/>	K:	
<input type="checkbox"/>	C:	
<input type="checkbox"/>	M:	
<input type="checkbox"/>	Y:	
<input type="checkbox"/>	K:	

Drugs Facts

Active ingredient Benzethonium chloride 0.10% (w/v)..... **Purpose** Antiseptic

Uses

- For washing sanitizing hands.
- Help to reduce bacteria on the skin that potentially can use disease.

Warnings

For external use only.

When using this product

Do not use

- On children less than 2 months of age.
- 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

- Wet as needed • Place enough product in your hand
- Rub gently for at least 30 seconds.
- Wash skin, rinse thoroughly and dry.

Other information

- Store at temperature below 110 F (43°C)

Inactive ingredients water (aqua), sodium lauryl ether sulfate, cocamidopropyl betaine, cocamide DEA, glycerin, propylene glycol, sodium chloride, citric acid, DMDM hydantoin.

MADE IN MEXICO
 Rosmar Químicos S de RL de CV
 Camino de los Volcanes 55, 4
 Matamoros, Coahuila, México

NDC 77251-008-02

rosmar USA

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

7 503030 502680

Fecha: 02 de diciembre 2020	Cliente: Química Rosmar	
Documento: Etiqueta NEUTROGEL 500 ml	Observaciones: Favor de presentar prueba de color en cuatricromía	

250 mL NDC: 77251-008-06

Colores:

C:	74
M:	40
Y:	30
K:	13
C:	90
M:	52
Y:	44
K:	38
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	

18 cm

12.8 cm

NEUTROGEL
Antibacterial Soap

KILLS 99.9% OF BACTERIA AND VIRUSES*

No dry or irritated skin
Residue free
Unscented
NETWT 33.8oz (250ml)

Drug Facts
Active Ingredient: Benzethonium chloride 0.13% (w/v) purpose: Antiseptic

Uses
•For washing sanitizing hands.
•Helps to reduce bacteria on the skin that potentially can cause disease.
•For use when soap and water are not available.

Warnings
For external use only.
Do not use:
•On children less than 2 months of age.
•On open skin wounds.

Directions
•Wet as needed • Place enough product in your hand
•Rub gently for at least 30 seconds.
•Wash skin, rinse thoroughly and dry.

Other information
•Store at temperature below 110 F (43°C)

Inactive ingredients water (aqua), sodium lauryl ether sulfate, cocamidopropyl betaine, cocamide DEA, glycerin, propylene glycol, sodium chloride, citric acid, DMDM hydantoin.

MADE IN MEXICO
Química Rosmar, S de RL
Carretera de los Valeros No. 100
Mexico City

NDC 77251-008-01

rosmar USA

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

7 503030 602224



Fecha: 26 de octubre 2020	Ciente: Química Rosmar	GCK Marketing solutions
Documento: Etiqueta BIOGERM 190g	Observaciones: Favor de presentar prueba de color en cuatricromía	

Colores:

C:	74
M:	40
Y:	30
K:	13
C:	90
M:	52
Y:	44
K:	38
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	
C:	
M:	
Y:	
K:	

NEUTROGEL[®]
Antibacterial Soap

KILLS 99.9% OF BACTERIA AND VIRUSES*

No dry or irritated skin
Residue free
Unscented
NETWT 6.762oz (200L)

Drug Facts
Active Ingredient: Benzethonium chloride 0.13% (w/v) purpose: Antiseptic

Uses
•For washing sanitizing hands.
•Helps to reduce bacteria on the skin that potentially can cause disease.

Warnings
For external use only.
Do not use:
•On children less than 2 months of age.
•On open skin wounds.

Directions
•Wet as needed • Place enough product in your hand
•Rub gently for at least 30 seconds.
•Wash skin, rinse thoroughly and dry.

Other information
•Store at temperature below 110 F (43°C)

Inactive ingredients water (aqua), sodium lauryl ether sulfate, cocamidopropyl betaine, cocamide DEA, glycerin, propylene glycol, sodium chloride, citric acid, DMDM hydantoin.

MADE IN MEXICO
Química Rosmar, S de RL
Carretera de los Valeros No. 100
Mexico City

NDC 77251-008-06

rosmar USA

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

7 503030 502856

Fecha: 02 de diciembre 2020	Ciente: Química Rosmar	GCK Marketing solutions
Documento: Etiqueta NEUTROGEL 200L	Observaciones: Favor de presentar prueba de color en cuatricromía	

NEUTROGEL

soap gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77251-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.1 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CHLORIDE (UNII: 451W471Q8X)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77251-008-01	4000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77251-008-02	200000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77251-008-03	20000 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77251-008-04	1000 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77251-008-05	500 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77251-008-06	250 mL in 1 POUCH; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

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

Establishment

Name	Address	ID/FEI	Business Operations
QUIMICA ROSMAR S.A DE C.V		8 14223475	manufacture(77251-008)

Revised: 1/2021

QUIMICA ROSMAR S.A DE C.V