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 leats 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

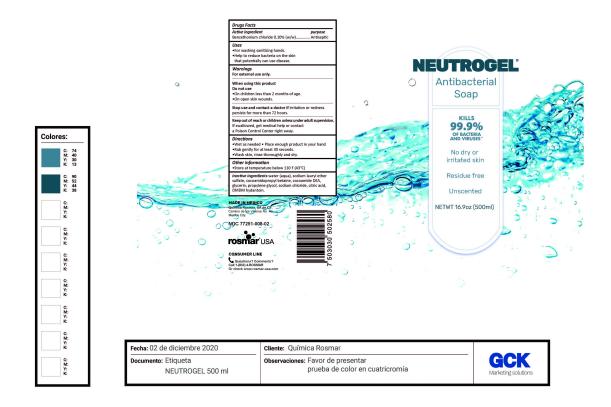


4000 mL NDC: 77251-008-01 200000 mL NDC: 77251-008-02 20000 mL NDC : 77251-008-03

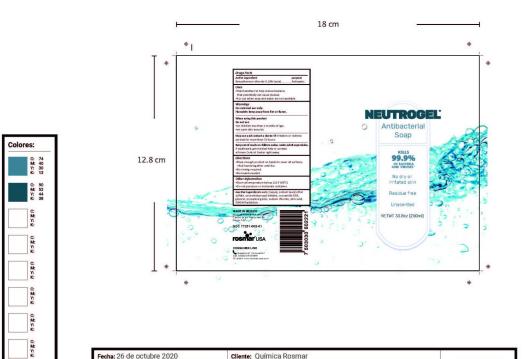


1000 mL NDC: 77251-008-04





250 mL NDC: 77251-008-06





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

C: M: Y: K:



NEUTROGEI oap gel							
Product Inform	ation						
Product Type		HUMAN OTC DRUG	Item Code (Source)			NDC:77251-008	
Route of Administ	ration	TOPICAL					
Active Ingredie	nt/Active Moi	ety					
		dient Name		Basis of Stren	gth	Strength	
BENZETHONIUM C UNII:1VU15B70BP)	HLORIDE (UNII: P	H41D05744) (BENZETHONIUM	-	BENZETHONIUM CHLORIDE	-	0.1 mg in 100 mL	
Inactive Ingred	iants						
mactive ingreu	icints	Ingredient Name				Strength	
COCO DIETHANOLAMIDE (UNII: 92005F972D)							
WATER (UNII: 059Q	F0KO0R)	,					
GLYCERIN (UNII: PI	DC6A3C0OX)						
SO DIUM LAURETH	SULFATE (UNII: I	3PV390UAP0)					
DMDM HYDANTO IN	N (UNII: BYR0546 T	OW)					
ANHYDRO US CITR	IC ACID (UNII: XF4	17D3PSL)					
PROPYLENE GLYC	OL (UNII: 6DC9Q	167V3)					
SODIUM CHLORID	E (UNII: 451W47IQ8	3X)					
COCAMIDOPROPY	L BETAINE (UNII:	50CF3011KX)					
Packaging							
# Item Code		Package Description		Marketing Start Date	Μ	arketing End Date	
1 NDC:77251-008- 01	Product	NTAINER; Type 0: Not a Combi	0	3/30/2020			
2 NDC:77251-008- 02	Product	CONTAINER; Type 0: Not a Cor	0	0 3/30 /20 20			
3 NDC:77251-008- 03	20000 mL in 1 CO Product	ONTAINER; Type 0: Not a Coml	bination 0	03/30/2020			
4 NDC:77251-008- 04		JCH; Type 0: Not a Combination		3/30/2020			
NDC.772E1 000	500 mL in 1 POU	CH; Type 0: Not a Combination	Product 0	03/30/2020			
 5 NDC:77251-008- 05 6 NDC:77251-008- 	500 mL m 1100	si, type of not a combination					

Marketing Information							
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
part333A	03/30/2020						
	Application Number or Monograph Citation	Application Number or Monograph Citation Marketing Start Date					

Establishment					
Name	Address	ID/FEI	Business Operations		
QUIMICA ROSMAR S.A DE C.V		814223475	manufacture(77251-008)		

Revised: 1/2021

QUIMICA ROSMAR S.A DE C.V