

SURGICAL AND HEALTHCARE PERSONNEL HAND ANTISEPTIC WITH MOISTURIZERS- alcohol liquid

EPOXEMEX, 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.

Surgical and Healthcare Sanitizer

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) (70%, 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. Chlorhexidine Gluconate (1%, volume/weight (v/w))
- c. Aloe Barbadensis Leaf Extract
- d. Fragrance
- e. Glycerin
- f. Polyethylene Glycol
- g. 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

Chlorhexidine Gluconate 1% v/w. Purpose: Antiseptic

Purpose

Surgical hand Antiseptic, Healthcare personnel hand Antiseptic

Use

Surgical Hand Antiseptic: significantly reduces the number of micro organisms on the hands and forearms prior to surgery or patient care.

Healthcare personnel Hand Antiseptic: handwash to help reduce bacteria that can potentially cause disease.

Warnings

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

Do not use

- If you are allergic to chlorhexidine gluconate or any other ingredient in this preparation.
- When using this product:
- Do not touch eyes with hands that have been treated with this preparation.
- Keep out of eyes, ears and mouth.
- May cause serious and permanent eye injury if permitted to enter and remain in eyes
- If contact occurs, rinse with cold water right away
- Do not use routinely if you have wounds which involve more than the superficial layers of the skin

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 and ask a doctor if irritation, sensitization or allergic reaction 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.

Directions

- **Use with care** in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
- **Surgical hand antiseptic** apply to clean, dry hands and nails. For the first use of each day, clean under nails with a nail stick, dispense one pump (2 ml) into the palm of one hand, dip the fingertips of the opposite hand into the lotion and work it under the nails, spread the remaining lotion over the hand and up to just above the elbow, using another 2 ml of lotion, repeat with the other hand, dispense another 2 ml of lotion into the other hand, reapply thoroughly to both hands up to the wrists. Allow to dry before donning gloves.
- **Healthcare personnel hand antiseptic** apply to clean, dry hands and nails, dispense one pump (2 ml) into the palm of one hand, paying particular attention to the spaces between the fingers and under fingernails, apply the product evenly to cover both hands up to the wrists, allow to dry without wiping.

Other information

- Store between 20-25C (68-77F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Polyethylene Glycol, purified water USP

Package Label - Principal Display Panel

1000 mL NDC: 79996-700-04



**SURGICAL AND HEALTHCARE
PERSONNEL
HAND ANTISEPTIC**



1L (33.81 FL OZ)





4000 mL NDC 79996-700-05



**SURGICAL AND HEALTHCARE
PERSONNEL
HAND ANTISEPTIC**



4L (135.2 FL OZ)



Creates a sanitizing barrier lasting up to 8 hours

20000 mL NDC 79996-700-06



SURGICAL AND HEALTHCARE PERSONNEL HAND ANTISEPTIC



20 L (5.283 Gal)



Creates a sanitizing barrier lasting up to 8 hours

1000 mL NDC: 79996-700-01





Surgical and healthcare Personnel Hand Antiseptic with moisturizers.

DO NOT USE if you allergic to chlorhexidine gluconate or any other ingredient in this preparation. Read Drug Facts Panel before use.



For External Use only



Surgical and Healthcare Personnel



1 L (33.81 FL OZ)

Surgical and Healthcare personnel Hand Antiseptic with moisturizers

Drug Facts

Active ingredient

Active ingredient	Purpose
Chlorhexidine Gluconate 1% v/w	Antiseptic
Ethyl alcohol 70% v/v	Antiseptic

Uses

▪ **surgical hand antiseptic:** significantly reduces the number of micro organism on the hands and forearms prior to surgery or patient care
▪ **healthcare personnel hand antiseptic:** handwash to help reduce bacteria that potentially can cause disease
▪ recommended for repeated use

Warnings

For external use only.

Flammable. Keep away from heat and flame

Do not use if you are allergic to chlorhexidine gluconate or any other ingredients in this preparation

When using this product • do not touch the eye with hands that have been treated with this preparation • keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye • if contact occurs, rinse with cold water right away • do not use routinely if you have wounds which involve more than the superficial layers of the skin

Stop use and ask a doctor if irritation, sensitization or allergic reaction 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.

Directions ▪ **Use with care** in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. ▪ **Surgical hand antiseptic** apply to clean, dry hands and nails. For the first use of each day, clean under nails with a nail stick , dispense one pump (2 ml) into the palm of one hand, dip the fingertips of the opposite hand into the lotion and work it under the nails, spread the remaining lotion over the hand and up to just above the elbow, using another 2 ml of lotion, repeat with the other hand, dispense another 2ml of lotion into other hand, reapply to all aspects of both hands up to the wrists. Allow to dry before donning gloves ▪ **Healthcare personnel hand antiseptic** apply to clean, dry hands and nails, dispense one pump (2 ml) into the palm of one hand, paying particular attention to the spaces between the fingers and under fingernails, apply the lotion evenly to cover both hands up to the wrists, allow to dry without wiping

Other information: ▪ Store at 20 -25°C, (68-77°F) ▪ Avoid excessive heat above 40°C (104°F) ▪ Keep container tightly closed

Inactive ingredients: ▪ Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Polyethylene Glycol, Water

Questions? Call 01-800-714-9531 Email: ventas@epoxemex.com

Manufactured by:

Epoxemex S.A de C.V.
Benito Juarez No. 735 Col. Santa Maria Aztahuacan
Alcaldia iztapalapa, Mexico City, C.P. 09500
Mexico

MADE IN MEXICO

Imported/Distributed by:



4000 mL NDC: 79996-700-02



Surgical and healthcare Personnel Hand Antiseptic with moisturizers.

DO NOT USE if you are allergic to chlorhexidine gluconate or any other ingredient in this preparation. Read Drug Facts Panel before use.



For External Use only



Surgical and Healthcare Personnel



4 L (135.2 FL OZ)

Surgical and Healthcare personnel Hand Antiseptic with moisturizers

Drug Facts

Active ingredient	Purpose
Chlorhexidine Gluconate 1% v/w	Antiseptic
Ethyl alcohol 70% v/v	Antiseptic

Uses

- **surgical hand antiseptic:** significantly reduces the number of micro organisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel hand antiseptic:** handwash to help reduce bacteria that can potentially cause disease
- recommended for repeated use

Warnings

For external use only.

Flammable. Keep away from heat and flame

Do not use if you are allergic to chlorhexidine gluconate or any other ingredient in this preparation

When using this product • do not touch eyes with hands that have been treated with this preparation • keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in eyes • if contact occurs, rinse with cold water right away • do not use routinely if you have wounds which involve more than the superficial layers of the skin

Stop use and ask a doctor if irritation, sensitization or allergic reaction 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.

Directions ▪ **Use with care** in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. ▪ **Surgical hand antiseptic** apply to clean, dry hands and nails. For the first use of each day, clean under nails with a nail stick, dispense one pump (2 ml) into the palm of one hand, dip the fingertips of the opposite hand into the lotion and work it under the nails, spread the remaining lotion over the hand and up to just above the elbow, using another 2 ml of lotion, repeat with the other hand, dispense another 2ml of lotion into other hand, reapply thoroughly to both hands up to the wrists. Allow to dry before donning gloves ▪ **Healthcare personnel hand antiseptic** apply to clean, dry hands and nails, dispense one pump (2 ml) into the palm of one hand, paying particular attention to the spaces between the fingers and under fingernails, apply the product evenly to cover both hands up to the wrists, allow to dry without wiping

Other information: ▪ Store at 20 -25°C, (68-77°F) ▪ Avoid excessive heat above 40°C (104°F) ▪ Keep container tightly closed

Inactive ingredients: ▪ Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Polyethylene Glycol, Water

Questions? Call 01-800-714-9531 Email: ventas@epoxemex.com

Manufactured by:
Epoxemex S.A de C.V.
Benito Juárez No. 735 Col. Santa María Azteca

20000 mL NDC: 79996-700-03



Surgical and healthcare Personnel Hand Antiseptic with moisturizers.

DO NOT USE if you are allergic to chlorhexidine gluconate or any other ingredient in this preparation. Read Drug Facts Panel before use.



Surgical and Healthcare personnel Hand Antiseptic with moisturizers

Drug Facts

Active ingredient	Purpose
Chlorhexidine Gluconate 1% v/w	Antiseptic
Ethyl alcohol 70% v/v	Antiseptic

Uses

- **surgical hand antiseptic:** significantly reduces the number of micro organisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel hand antiseptic:** handwash to help reduce bacteria that can potentially cause disease
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Stop use and ask a doctor if irritation, sensitization or allergic reaction 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.

Directions ▪ **Use with care** in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns. ▪ **Surgical hand antiseptic** apply to clean, dry hands and nails. For the first use of each day, clean under nails with a nail stick, dispense one pump (2 ml) into the palm of one hand, dip the fingertips of the opposite hand into the lotion and work it under the nails, spread the remaining lotion over the hand and up to just above the elbow, using another 2 ml of lotion, repeat with the other hand, dispense another 2ml of lotion into other hand, reapply thoroughly to both hands up to the wrists. Allow to dry





20 L (5.283 Gal)

before donning gloves ■ **Healthcare personnel hand antiseptic** apply to clean, dry hands and nails, dispense one pump (2 ml) into the palm of one hand, paying particular attention to the spaces between the fingers and under fingernails, apply the product evenly to cover both hands up to the wrists, allow to dry without wiping

Other information: ■ Store at 20 -25°C, (68-77°F) ■ Avoid excessive heat above 40°C (104°F) ■ Keep container tightly closed

Inactive ingredients: ■ Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Polyethylene Glycol, Water

Questions? Call 01-800-714-9531 Email: ventas@epoxemex.com



Manufactured by:
Epoxemex S.A de C.V.
Benito Juarez No. 735 Col. Santa Maria Aztahuacan
Alcaldia iztapalapa, Mexico City, C.P. 09500
Mexico
MADE IN MEXICO
Imported/Distributed by:

SURGICAL AND HEALTHCARE PERSONNEL HAND ANTISEPTIC WITH MOISTURIZERS

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79996-700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	1 g in 100 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79996-700-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
2	NDC:79996-700-02	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021

3	NDC:79996-700-03	20000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	12/31/2021
4	NDC:79996-700-04	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
5	NDC:79996-700-05	4000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	
6	NDC:79996-700-06	20000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2021	

Marketing Information

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

Labeler - EPOXEMEX, S.A. DE C.V. (814573127)

Registrant - AY CONSULTING SERVICES, LLC (078311971)

Establishment

Name	Address	ID/FEI	Business Operations
EPOXEMEX, S.A. DE C.V.		814573127	manufacture(79996-700)

Revised: 6/2022

EPOXEMEX, S.A. DE C.V.