

BY BY BACTER HAND SANITIZER- alcohol gel
Distribuidora y Comercializadora AGBHAL, 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.

By - By Bacter Hand Sanitizer

By - By Bacter hand sanitizer

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

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

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.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, carbomer, triethanolamine, purified water USP

Package Label - Principal Display Panel

The label features a blue and white color scheme with a red banner. At the top, a blue oval contains the brand name 'By-By Bacter' in white and blue. Below this, the words 'hand Sanitizer' are written in a large, bold, black font, followed by 'Non-sterile Solution' in a smaller black font. A red banner across the middle contains the text 'Kills 99.9% of Germs*'. To the right of the banner is a circular seal with '80% ETHYL ALCOHOL ANTISEPTIC' and 'TOPICAL SOLUTION' around the perimeter. Below the banner is another circular seal with 'ANTIBACTERIAL SANITIZER' around the perimeter. In the bottom left corner, the volume '33.8 Fl OZ' and '1 L' is printed. The right side of the label contains a 'DRUG FACTS' table, a list of directions, other information, and inactive ingredients. At the bottom right, there is a barcode with the numbers '7 502278 002906' and a lot/expiration date: 'Lot: # 0001 EXP. DATE April 2025'. Several hazard and handling icons are also present.

By-By Bacter

hand Sanitizer
Non-sterile Solution

Kills 99.9% of Germs*

33.8 Fl OZ
1 L

80%
ETHYL ALCOHOL
ANTISEPTIC
TOPICAL SOLUTION

ANTIBACTERIAL
SANITIZER

| DRUG FACTS | |
|--|------------|
| Active Ingredient(s) | Purpose |
| Ethyl Alcohol 80% v/v..... | Antiseptic |
| Use(s) | |
| Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| WARNINGS | |
| For external use only. Flammable. Keep away from heat or flame. | |
| Do not use | |
| • In children less than 2 months of age. | |
| • On open skin wounds when using this product. | |
| 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. | |
| Directions | |
| • Place enough product on hands to cover all surfaces. Rub hands together until dry. | |
| • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| Other information | |
| • Store between 15-30°C (59-86°F). | |
| • Avoid freezing and excessive heat above 40°C (104°F). | |
| Inactive Ingredients: Glycerin, Carbomer, Triethanolamine, Purified Water USP. | |
| * Effective at eliminating 99.9% of many common harmful germs & bacteria in as little as 30 seconds. | |
| Made in Mexico by Distribuidora y Comercializadora Agbhal S.A. de C.V. Avenida De La Carreta 815, Parque Industrial Belenes, Zapopan, Jalisco. Distributed in the U.S.A. by: Four Titans LLC The Woodlands, Tx 77382, Texas Phone 832 450 9523 evangelosanchez@fourtitansllc.com | |
| | |
| Lot: # 0001 EXP. DATE April 2025 | |
| | |
| 7 502278 002906 | |



hand Sanitizer

Non-sterile Solution



Kills 99.9% of Germs*

128 FL OZ
(1 GALLON)
3.78L



DRUG FACTS

| Active Ingredient(s) | Purpose |
|-----------------------|------------|
| Ethyl Alcohol 80% w/v | Antiseptic |

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Lot: # 0001
EXP. DATE April 2025





hand Sanitizer

Non-sterile Solution



Kills 99.9% of Germs*



10.9 Fl Oz
325 ml

DRUG FACTS

| Active Ingredient(s) | Purpose |
|-----------------------|------------|
| Ethyl Alcohol 80% v/v | Antiseptic |

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Lot: # 0001
EXP. DATE April 2025



500 ml NDC: 79104-002-04



hand Sanitizer

Non-sterile Solution



Kills 99.9% of Germs*

16.9 Fl Oz
500 ml



DRUG FACTS

Active Ingredient(s) Purpose
Ethyl Alcohol 80% v/v..... Antiseptic

Use(s)
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Lot: # 0001
EXP. DATE April 2025



BY BY BACTER HAND SANITIZER

alcohol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|-----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79 10 4-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 80 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|------------------|
| TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA) | 0.3 mL in 100 mL |
| GLYCERIN (UNII: PDC6A3C0OX) | 2 mL in 100 mL |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) | 0.3 mL in 100 mL |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|--|----------------------|--------------------|
| 1 | NDC:79 104-002-01 | 1000 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 2 | NDC:79 104-002-02 | 3780 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 3 | NDC:79 104-002-03 | 325 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/30/2020 | |
| 4 | NDC:79 104-002-04 | 500 mL in 1 BOTTLE; 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 - Distribuidora y Comercializadora AGBHAL, S.A. de C.V. (951576855)

Registrant - Distribuidora y Comercializadora AGBHAL, S.A. de C.V. (951576855)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---------|-----------|-------------------------|
| Distribuidora y Comercializadora AGBHAL, S.A. de C.V. | | 951576855 | manufacture(79 104-002) |

Revised: 8/2020

Distribuidora y Comercializadora AGBHAL, S.A. de C.V.