# PHM SAFE- alcohol solution PHM Brands, LLC

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.

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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)

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

## **Inactive ingredients**

glycerin, hydrogen peroxide, purified water USP

## Package Label - Principal Display Panel

PHM Safe Hand Sanitizer 16oz.16 oz (473 mL) NDC: 78795-001-16Package Label.Principal Display Panel

| SAFE   | nd bacteria.<br>Purpose<br>of available.   |
|--|--|
| HAND<br>Sanitizer  | mful germs are<br>res, thee eves thoroug<br>ical Center right away.  |
| NON-STERILE SOLUTION   | / common har<br>disease. For use whe<br>me<br>the signs of a seriour of<br>contract a Potion Curl<br>ds together until dy.<br>uct to avoid swillowing<br>water USP   |
| 99.99% OA  | Effective at eliminating 99.99% of many common harmful germs and bacteria.         Drag Facts       Pau         Active inpredient(s)       Pau         In collidron lease not, filamentals, Kapp away from heat or filame       Pau         Paramage       Pau         Paramage       Pau         Paramage       Pau         Paramage       Pau         Paramage       Pau         Paramage       Pau         Pau       Pau  |
|  | Effective at eliminating 99.99% of<br>Drug facts<br>Active inpredient(s)<br>Active inpredient(s)<br>Active intervention<br>in cliniter to help reduce bacteria that potentially.<br>Hand sentisf<br>in children less than 2 months of age<br>Den et annality and power fammable. Keep away from he<br>Den et annality and the analytic fammable. Keep away from he<br>Den et annality and the analytic fammable. Keep away from he<br>Den et annality and the analytic fammable. Keep away from he<br>Den et annality and the analytic fammable. Keep away from he<br>Den et annality and an et an and the analytic fam and an<br>Stop were and ak a doctor if infratision or real or and normal<br>these and ak a doctor if infratision or real occur. If<br>Detections<br>are the enough product con hands to corer all surfaces.<br>If supervise children under 6 years of age when using it<br>as the the information<br>Best the information of the active and exceeded heat a growed doc (1004)<br>intocher ingeredients giventiv, hydrogen peroded.   |
|  | *Effective at elim<br>Pug Facts at elim<br>Active ingredient[s]<br>Accine 180% v/v<br>Lute [s]<br>Lute [s]<br>Lute [s]<br>Lute [s]<br>Lute [s]<br>Lute [s]<br>Ven maing an elim<br>Ven maing an elim<br>Step ues and ak a doct<br>Step ues and ak a doct<br>Step ves and ak a doct<br>Resp out of resch of cia<br>Place enough product<br>B stone enou |
|  | PHN<br>MANUFACTURED BY:<br>VOBIN, LLC.<br>VOBIN, LLC.<br>VOBIN, LLC.<br>20016, 11, 6655<br>844-215-8562<br>844-215-8562<br>844-215-8562<br>844-215-8562<br>844-215-8562<br>844-215-8562<br>844-215-8562<br>844-215-8562  |
| ALCOHOL ANTISEPTIC 80%<br>TOPICAL SOLUTION<br>NET CONTENTS: 16 OZ (473 ML) | PHN<br>MANUTACT<br>VIOBIN LL<br>2001010<br>844-215-853<br>844-215-853<br>www.phms  |

| Route of Administration       TOPICAL         TOPICAL         Active Ingredient/Active Moiety         Ingredient Name         ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)         Ingredient Name         ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)         Ingredient Name         GLYCERIN (UNII: PDC6A3C0OX)         HYDRO GEN PERO XIDE (UNII: BBX060AN9V)         WATER (UNII: 059QF0K00R)         Fackaging         Item Code         Package Description   | Basis of Streng<br>ALCOHOL | 80 L in 100 L Strength                    |  |
|---|----------------------------|---|--|
| Product Type       HUMAN OTC DRUG       Item Col         Route of Administration       TOPICAL       Human of Col         Active Ingredient/Active Moietty       Ingredient Name       Ingredient Name         ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)       Ingredient Name       Ingredient Name         ALCOHOL (UNII: 3K958V90M) (ALCOHOL - UNII:3K9958V90M)       Ingredient Name       Ingredient Name         Ingredients       Ingredient Name       Ingredient Name         Ingredient Ingredients       Ingredient Name       Ingredient Name         GLYCERIN (UNII: PDC6 A3C00 X)       Ingredient Name       Ingredient Name         Ingredient Ingredients       Ingredient Name       Ingredient Name         GLYCERIN (UNII: PDC6 A3C00 X)       Ingredient Name       Ingredient Name         Ingredient Ingredient Ingredient Ingredient Ingredient Name       Ingredient Name       Ingredient Name         Ingredient Ingre | Basis of Streng<br>ALCOHOL | gth Strength<br>80 L in 100 L<br>Strength |  |
| Route of Administration TOPICAL     A ctive Ingredient/Active Moietter   Ingredient Name  | Basis of Streng<br>ALCOHOL | gth Strength<br>80 L in 100 L<br>Strength |  |
| A ctive Ingredient/Active Moiety<br>Ingredient Name<br>ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)<br>ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)<br>Inactive Ingredients<br>Ingredient Name<br>GLYCERIN (UNII: PDC6 A3C00X)<br>HYDRO GEN PERO XIDE (UNII: BBX060AN9V)<br>WATER (UNII: 059QF0K00R)<br>Packaging<br>I tem Code Package Description<br>1 NDC:78759-001- 473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination   | ALCOHOL                    | 80 L in 100 L Strength                    |  |
| Ingredient Name         ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)         Ingredient Name         Ingredient Name         GLYCERIN (UNII: PDC6A3C00X)         HYDRO GEN PERO XIDE (UNII: BBX060AN9V)         WATER (UNII: 059QF0K00R)         Packaging         #       Item Code       Package Description         1       NDC:78759-001-       .473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination  | ALCOHOL                    | 80 L in 100 L Strength                    |  |
| Ingredient Name         ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)         Ingredient Name         Ingredient Name         GLYCERIN (UNII: PDC6A3C0OX)         HYDRO GEN PERO XIDE (UNII: BBX060AN9V)         WATER (UNII: 059QF0K00R)         Packaging         #       Item Code       Package Description         1       NDC:78759-001-       .473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination  | ALCOHOL                    | 80 L in 100 L Strength                    |  |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)<br>Inactive Ingredients<br>Ingredient Name<br>GLYCERIN (UNII: PDC6A3C00X)<br>HYDROGEN PEROXIDE (UNII: BBX060AN9V)<br>WATER (UNII: 059QF0K00R)<br>WATER (UNII: 059QF0K00R)<br>I Item Code Package Description<br>1 NDC:78759-001- 473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination   | ALCOHOL                    | 80 L in 100 L Strength                    |  |
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| GL YCERIN (UNII: PDC6A3C0OX)<br>HYDRO GEN PERO XIDE (UNII: BBX060AN9V)<br>WATER (UNII: 059QF0K00R)<br>Packaging<br>I tem Code Package Description<br>1 NDC:78759-001473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination   | 1 AF T                     | •   |  |
| GLYCERIN (UNII: PDC6A3C0OX)<br>HYDROGEN PEROXIDE (UNII: BBX060AN9V)<br>WATER (UNII: 059QF0K00R)<br>Packaging<br># Item Code Package Description<br>1 NDC:78759-001- 473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination   | 1 4F T - 10                | •   |  |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V)<br>WATER (UNII: 059QF0K00R)<br>Packaging<br># Item Code Package Description<br>1 NDC:78759-001473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination  | 1451 m ll                  | 00 L                                      |  |
| WATER (UNII: 059QF0K00R) Packaging # Item Code Package Description 1 NDC:78759-001473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination   |                            | 1.45 L in 100 L<br>0.125 L in 100 L       |  |
| Packaging         #       Item Code       Package Description         1       NDC:78759-001-       .473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination   | 18.425 L in                | 18.425 L in 100 L                         |  |
| #     Item Code     Package Description       1     NDC:78759-001-     .473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination   |                            |   |  |
| ,   | Marketing Start<br>Date    | Marketing End<br>Date                     |  |
|   | 09/14/2020                 |   |  |
|   |                            |   |  |
| Marketing Information   |                            |   |  |
| Marketing CategoryApplication Number or Monograph CitationOTC monograph not finalpart333A   | Marketing Start Date       | Marketing End Da                          |  |

# Labeler - PHM Brands, LLC (081176131)

| Establishment |         |           |   |  |
|---------------|---------|-----------|---|--|
| Name          | Address | ID/FEI    | Business Operations                     |  |
| Viobin, LLC   |         | 805279234 | manufacture(78759-001), pack(78759-001) |  |

Revised: 9/2020

PHM Brands, LLC