

HARUHOME HAND SANITIZER- alcohol liquid

George K Hood 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.

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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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



PASSION
LABELS AND PACKAGING, INC.

| | | | | | | | | | | |
|---|--|--|---------------|-----------------|----------------|---------------|---|---|---|---|
| Proof Key <input type="checkbox"/> Dieline (Does Not Print) <input type="checkbox"/> Color Bleed (see #3 >) <input type="checkbox"/> Clear Space (see #4 >) <input type="checkbox"/> Areas Backed in White | NOTES:* | | | | | | | | | |
| | | | | | | | | | | |
| Passion Labels & Packaging, Inc. 1223 Tallevast Rd. • Sarasota, FL 34243 (941) 312-5003 Toll Free: (888) 425-3955 Fax: (941) 312-5059 | PRODUCT INFORMATION Art/Job ID: 11162 Date: 04/09/2020cl Cust/Prod: XZON / Haruhome - Haruhome Hand Sanitizer Unscented 4oz Spray Method: Digital Material: 2.6 mil Pearl White BOPP Film / Perm adh / 40# liner Overcoat: 1.5 mil Matte Polypropylene Lam OD / CT: 1,000/Roll Size: 3.5" x 4.5" w/ .125" corner radius Signature _____ Date _____ | COLORS <table border="1" style="width: 100%;"> <tr> <td style="background-color: cyan;">Process Cyan</td> <td style="background-color: magenta;">Process Magenta</td> <td style="background-color: yellow;">Process Yellow</td> <td style="background-color: black;">Process Black</td> </tr> <tr> <td style="text-align: center;">.</td> <td style="text-align: center;">.</td> <td style="text-align: center;">.</td> <td style="text-align: center;">.</td> </tr> </table> Notes: _____ | Process Cyan | Process Magenta | Process Yellow | Process Black | . | . | . | . |
| Process Cyan | Process Magenta | Process Yellow | Process Black | | | | | | | |
| . | . | . | . | | | | | | | |
| Dispensing Direction #4 Unwind = Left First | PROOF APPROVAL Please check all that apply <input type="checkbox"/> SIZE LISTED IS CORRECT <input type="checkbox"/> UPC IS CORRECT (if applicable) <input type="checkbox"/> DISPENSE DIRECTION CORRECT <input type="checkbox"/> SPELLING IS ALL CORRECT <input type="checkbox"/> COLORS LISTED ARE CORRECT <input type="checkbox"/> OK... PER PROOF <input type="checkbox"/> OK... WITH CHANGES INDICATED <input type="checkbox"/> PLEASE SUBMIT ANOTHER PROOF NOTICE: This proof is for layout and copy only. It does not reflect actual color, or the exact color achievable on press. | | | | | | | | | |

* Notes are strictly FYI. They are neither to be considered critique nor commentary on art provided. They are written directly on the proofs so that:

- You know immediately if there is a fatal artwork error that must be fixed before moving to print.
- If/what fixes were made by the art dept. to print to your specs.
- If you wish to correct your native files you have something from which to work.
- To help you identify and correct recurring accidents.

THANK YOU

FROM YOUR TEAM AT
 PASSION LABELS & PACKAGING, INC.

118.294 mL NDC: 7490-001-04

HARUHOME HAND SANITIZER

alcohol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:74950-003 |
| 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 |
|--------------------------------------|--------------------|
| GLYCERIN (UNII: PDC6A3C0OX) | 1.45 mL in 100 mL |
| HYDROGEN PEROXIDE (UNII: BBX060AN9V) | 0.125 mL in 100 mL |
| WATER (UNII: 059QF0K00R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|-----------------------------|---------------------------|
| 1 | NDC:74950-003-04 | 118.294 mL in 1 BOTTLE, SPRAY; 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 - George K Hood LLC (122360994)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|----------------|---------------|----------------------------|
| George K Hood Legacy LLC | | 122360994 | manufacture(74950-003) |

Revised: 4/2020

George K Hood LLC