

## **BERKLEY JENSEN INSTANT SANITIZER- ethyl alcohol liquid BJWC**

*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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### **Drug Facts**

#### **Active ingredient**

Ethyl Alcohol 65%

#### **Purpose**

Antiseptic

#### **Uses**

to help reduce bacteria on the skin.

#### **Warnings**

- for external use only
- flammable
- keep away from source of heat or fire

#### **When using this product**

avoid contact with eyes. If contact occurs, rinse with water.

Stop using this product and ask doctor if irritation or redness develops and lasts.

*Keep out of reach of children.*

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

#### **Directions**

wet hands thoroughly and rub together until dry.

#### **Other information**

store at a temperature below 110°F (43°C)

#### **Inactive ingredients**

Water (Aqua), Isopropyl Alcohol, Glycerin, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol, Fragrance (Parfum).

#### **Questions or comments?**

1-800-934-1204

## Label Copy

**berkley jensen®**

**INSTANT HAND SANITIZER**

**KILLS 99.99% OF GERMS**

2 FL OZ (59 mL)

06-20168

| Drug Facts                                                                                                                                                                                       |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Active ingredient</b>                                                                                                                                                                         | <b>Purpose</b> |
| Ethyl Alcohol 65%.....                                                                                                                                                                           | Antiseptic     |
| <b>Uses</b> to help reduce bacteria on the skin                                                                                                                                                  |                |
| <b>Warnings</b>                                                                                                                                                                                  |                |
| ■ For external use only. ■ Flammable. ■ Keep away from source of heat or fire.                                                                                                                   |                |
| <b>When using this product</b> avoid contact with eyes. If contact occurs, rinse with water.                                                                                                     |                |
| <b>Stop using this product and ask doctor</b> if irritation or redness develops and lasts.                                                                                                       |                |
| <b>Keep out of reach of children.</b> In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.                                                          |                |
| <b>Directions</b> wet hands thoroughly and rub together until dry.                                                                                                                               |                |
| <b>Other information</b> store at a temperature below 110°F (43°C).                                                                                                                              |                |
| <b>Inactive ingredients</b> Water (Aqua), Isopropyl Alcohol, Glycerin, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol, Fragrance (Parfum). |                |
| <b>Questions or comments?</b> 1-800-934-1204                                                                                                                                                     |                |

Distributed by: BJ's Wholesale Club  
25 Research Drive, Westborough, MA 01581  
Questions? 1-800-934-1204  
Made in Canada

06-23005

## Label Copy

**berkley jensen®**

**INSTANT HAND SANITIZER**

**KILLS 99.99% OF GERMS**

12 FL OZ (354 mL)

06-20170

| Drug Facts                                                                                                                                                                                       |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| <b>Active ingredient</b>                                                                                                                                                                         | <b>Purpose</b> |
| Ethyl Alcohol 65%.....                                                                                                                                                                           | Antiseptic     |
| <b>Uses</b> to help reduce bacteria on the skin.                                                                                                                                                 |                |
| <b>Warnings</b>                                                                                                                                                                                  |                |
| ■ For external use only. ■ Flammable. ■ Keep away from source of heat or fire.                                                                                                                   |                |
| <b>When using this product</b> avoid contact with eyes. If contact occurs, rinse with water.                                                                                                     |                |
| <b>Stop using this product and ask doctor</b> if irritation or redness develops and lasts.                                                                                                       |                |
| <b>Keep out of reach of children.</b> In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.                                                          |                |
| <b>Directions</b> wet hands thoroughly and rub together until dry.                                                                                                                               |                |
| <b>Other information</b> store at a temperature below 110°F (43°C).                                                                                                                              |                |
| <b>Inactive ingredients</b> Water (Aqua), Isopropyl Alcohol, Glycerin, Isopropyl Myristate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Carbomer, Aminomethyl Propanol, Fragrance (Parfum). |                |
| <b>Questions or comments?</b> 1-800-934-1204                                                                                                                                                     |                |

Distributed by: BJ's Wholesale Club  
25 Research Drive, Westborough, MA 01581  
Questions? 1-800-934-1204 Made in Canada

06-23006

## BERKLEY JENSEN INSTANT SANITIZER

ethyl alcohol liquid

| Product Information     |  |                |                    |               |
|-------------------------|--|----------------|--------------------|---------------|
| Product Type            |  | HUMAN OTC DRUG | Item Code (Source) | NDC:68391-167 |
| Route of Administration |  | TOPICAL        |                    |               |

  

| Active Ingredient/Active Moiety                        |                   |                |
|--------------------------------------------------------|-------------------|----------------|
| Ingredient Name                                        | Basis of Strength | Strength       |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL           | 650 mg in 1 mL |

  

| Inactive Ingredients                               |          |
|----------------------------------------------------|----------|
| Ingredient Name                                    | Strength |
| WATER (UNII: 059QF0KO0R)                           |          |
| ISOPROPYL ALCOHOL (UNII: ND2M416302)               |          |
| GLYCERIN (UNII: PDC6A3C0OX)                        |          |
| CARBOMER 934 (UNII: Z135WT9208)                    |          |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q)             |          |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)             |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                  |          |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) |          |

  

| Packaging |                  |                                                                |                      |                    |
|-----------|------------------|----------------------------------------------------------------|----------------------|--------------------|
| #         | Item Code        | Package Description                                            | Marketing Start Date | Marketing End Date |
| 1         | NDC:68391-167-03 | 59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 05/27/2017           |                    |
| 2         | NDC:68391-167-13 | 354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 05/27/2017           |                    |

  

| Marketing Information   |                                          |                      |                    |
|-------------------------|------------------------------------------|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333E                                 | 05/27/2017           |                    |

**Labeler** - BJWC (159082692)

**Registrant** - Apollo Health and Beauty Care Inc. (201901209)

## Establishment

| Name                               | Address | ID/FEI    | Business Operations    |
|------------------------------------|---------|-----------|------------------------|
| Apollo Health and Beauty Care Inc. |         | 201901209 | manufacture(68391-167) |