**SHSNH6-5111- benzalkonium chloride solution**
**Shotwell Hydrogenics, 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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**SHSNH6-5111 Alcohol-Free Foaming Hand Sanitizer Antimicrobial Foaming Solution**

***Drug Facts***

***Active ingredients(s)***

Benzalkonium Chloride 0.13%

***Purpose***

Antimicrobial

**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.

**Do not use**

• in children less than 2 months of age

• on open skin wounds

**When using this product** avoid contact with eyes. In case of contact with eyes, rinse eyes thoroughly with water.

**Stop use and ask for a doctor** if irritation or redness develops, or if condition persists for more than 72 hours.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

• Pump a small amount of foam into palm of hand.

• Rub thoroughly over all surfaces of both hands

• Continue to rub hands until dry.

***Inactive ingredients***

deionized water, glycerin, aloe barbadensis leaf juice, lauramine oxide, dimethyltetradecylamine oxide, fragrance, DMDM hydantoin (preservative).

**Alcohol-Free Foaming Hand Sanitizer**

**Antimicrobial Foaming Solution**

## Packaging

| ***Drug Facts*** | |
|---|---|
| ***Active ingredients(s)*** | ***Purpose*** |
| Benzalkonium Chloride 0.13%..... | Antimicrobial |

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## SHSNH6-5111

benzalkonium chloride solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:73870-201 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - | BENZALKONIUM | 1.3 g |

| | | |
|---|---|---|
| UNII:7N6JUD5X6Y) | CHLORIDE | in 1 L |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **LAURAMINE OXIDE** (UNII: 4F6FC4MI8W) | |
| **MYRISTAMINE OXIDE** (UNII: J086PM3RRT) | |
| **DMDM HYDANTOIN** (UNII: BYR0546TOW) | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:73870-201-33 | 1249 L in 1 CONTAINER; Type 0: Not a Combination Product | 10/05/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333A | 10/05/2020 | |

## Labeler - Shotwell Hydrogenics, LLC (108985732)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Shotwell Hydrogenics, LLC | | 108985732 | manufacture(73870-201) |

Revised: 11/2020 Shotwell Hydrogenics, LLC