

## **HAND SANITIZER- benzalkonium chloride liquid**

**West One Logistics, 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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### **BZK Hygen-x**

#### **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.

#### **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

## Safe Handling

Keep out of reach of children.

## Package Label - Principal Display Panel

3774 mL NDC: 77856-001-01 JPEG

<p><b>Drug Facts</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">Active Ingredient(s)</th> <th style="text-align: left;">Purpose</th> </tr> <tr> <td>Benzalkonium Chloride, 13%</td> <td>Antiseptic</td> </tr> </table> <p><b>Use(s)</b> Handwash to help reduce bacteria that potentially can cause disease. Helps to prevent cross-contamination by hand contact. Helps to prevent drying of the skin. Recommended for repeated use.</p> <p><b>Warnings</b> For external use only. Avoid contact with eyes. <b>Do not use</b> 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. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> Apply an appropriate amount of product into palm of hand. Rub thoroughly over all surface of both hands for at least 20 seconds. Rub hands together until dry.</p> <p><b>Other information</b> Store in a cool, dry place below 104°F (40° C)</p> <p><b>Inactive Ingredients</b> water, glycerin, carbomer, isopropyl myristate.</p>	Active Ingredient(s)	Purpose	Benzalkonium Chloride, 13%	Antiseptic	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Natural Fragrances • Free of Dyes</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">EXTERNAL USE ONLY</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">DO NOT DRINK</p>	<h1 style="margin: 0;">HYGEN-X</h1> <div style="background-color: red; color: white; padding: 5px; margin: 5px 0;">BZK SANITIZER</div> <p style="margin: 0;"><b>Topical Non-Sterile Solution</b> 8 fl. oz. (237 ml)</p>	<p style="font-size: 8px;">This product and its label are in compliance with the regulations set forth by the</p>
Active Ingredient(s)	Purpose						
Benzalkonium Chloride, 13%	Antiseptic						
<p style="font-size: 8px;">7 61245 06488 1</p>	<p style="font-size: 8px;">DIST BY: <b>West One Logistics</b> 7965 Silverton Ave Suite 1310 San Diego, CA 92126 www.hygenxlife.com</p>	<p style="font-size: 8px;">Third Party Verified, Backed by American Quality</p> <p style="font-size: 8px;">SCAN TO VERIFY</p>					

## HAND SANITIZER

benzalkonium chloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:77856-6866
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	5 mg in 3785 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	1.9 mg in 3785 mg
<b>FRAGRANCE LAVENDER &amp; CHIA F-153480</b> (UNII: SXS9CO2TZK)	3.8 mg in 3785 mg
<b>WATER</b> (UNII: 059QF0K00R)	3774 mg in 3785 mg

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77856-6866-1	3785 mg in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - West One Logistics, LLC. (117523353)

**Registrant** - West One Logistics, LLC. (117523353)

## Establishment

Name	Address	ID/FEI	Business Operations
West One Logistics, LLC.		117523353	manufacture(77856-6866)

Revised: 9/2020

West One Logistics, LLC.