

**ULTRACRUZ ANTIBACTERIAL HAND NONE- benzalkonium chloride soap**  
**Cixi Zhixin Bird Clean-care Product Co., Ltd.**

*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.*

-----

**Antibacterial Hand Soap**

Active Ingredient:

Benzalkonium Chloride 0.1%

Purpose:

Antiseptic

Uses:

For hand washing to kill bacterial on the skin

Warnings

For external use only

Flammable. Keep away from fire or flame

Do not apply around eyes. Do not use in ears & mouth

When using this product, avoid contact with eyes. In case of contact, flush eyes with water

Stop use and see a doctor if irritation or redness develop and persist for more than 72 hours

Keep out of reach of children. Children must be supervised in use of this product.

Directions:

Wet hands, apply to palms, scrub thoroughly, then rinse.

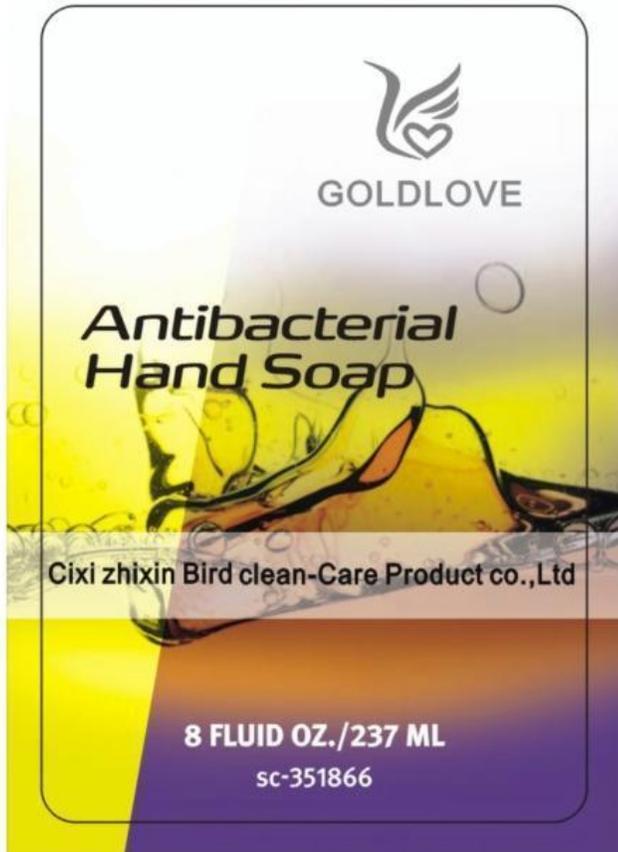
Other Information:

Store at 20C (68-77F). May discolor fabrics

Inactive Ingredient:

Deionized water, Sodium lauryl polyoxyethylene ether sulfate, Sodium fatty alcohol ethyl sulfate, Cocoamidopropyl

betaine, Carboxymethylcellulose sodium, DMDM Hydantoin, Glycerol, Frangance



**8oz ANTIBACTERIAL HAND SOAP**

**Drug Facts** Lot# 04142133

<b>Active Ingredient</b>	<b>Purpose</b>
Benzalkonium Chloride 0.10%.....	Antiseptic
<b>Uses:</b> For handwashing to decrease bacteria on the skin.	
<b>Warnings</b>	
For external use only.	
Do not apply around eyes. Do not use in ears & mouth.	
When using this product, avoid contact with eyes.	
In case of contact flush eyes with water.	
Stop use and ask a doctor if redness or irritation develop and persist for more than 72 hours.	
Keep out of reach of children. Children must be supervised in use of this product.	
<b>Directions:</b> Wet hands, apply to palms and scrub thoroughly, then rinse.	
<b>Other Information:</b> Store at 20° C (68° to 77° F). May discolor fabrics.	
<b>Inactive Ingredients:</b> Deionized water, Benzalkonium Chloride, Sodium lauryl polyoxyethylene ether sulfate, Sodium Fatty Alcohol Ether Sulfate, Cocoamidopropyl Betaine, Carboxymethylcellulose sodium, DMDM Hydantoin, Glycerol, Fragrance,	

Cixi zhixin Bird clean-Care Product co.,Ltd Made in China

## ULTRACRUZ ANTIBACTERIAL HAND NONE

benzalkonium chloride soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49877-012
<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	0.1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	72.525 g in 100 mL
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>GLYCEROL FORMAL</b> (UNII: 3L7GR2604E)	
<b>LAURAMIDOPROPYL BETAINE</b> (UNII: 23D6XVI233)	
<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49877-012-01	237 mL in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/22/2014	

**Labeler** - Cixi Zhixin Bird Clean-care Product Co., Ltd. (529823986)**Registrant** - Cixi Zhixin Bird Clean-care Product Co., Ltd. (529823986)**Establishment**

Name	Address	ID/FEI	Business Operations
Cixi Zhixin Bird Clean-care Product Co., Ltd.		529823986	manufacture(49877-012)

Revised: 8/2014

Cixi Zhixin Bird Clean-care Product Co., Ltd.